THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 3

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

KENNETH A. BARTON and MICHAEL J. MILLER, (U.S. Application 07/827,906)

(Barton),

or

MAILED

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

DAVID A. FISCHHOFF and FREDERICK J. PERLAK, (U.S. Application 08/434,105)

Junior Party (Fischhoff),

v.

MICHAEL J. ADANG, THOMAS A. ROCHELEAU, DONALD J. MERLO, and ELIZABETH E. MURRAY, (U.S. Patent 5,380,831)

Senior Party (Adang)

Interference 103,781

Final Hearing: September 26, 2003

Before: GRON, <u>Administrative Patent Judge</u>, SPIEGEL, <u>Administrative Patent Judge</u>, and NAGUMO, <u>Administrative Patent Judge</u>

GRON, Administrative Patent Judge.

FINAL HEARING AND ORDER

1. <u>Summary</u>

We grant Fischhoff's uncontested Preliminary Motion 10 to amend Count 2 both with respect to Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and with respect to Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11). Count 2 is ordered amended to exclude Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105 and Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11). Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105 and Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11) are designated as not corresponding to amended Count 2.

With respect to priority of the invention of amended

Count 2, the preponderance of evidence of record establishes:

- A. Senior Party Adang first reduced the invention of amended Count 2 to practice constructively on September 9, 1988, the filing date of Adang's grandparent U.S. Application 07/242,482, now abandoned;
- B. Junior Party Fischhoff actually reduced the invention of amended Count 2 to practice prior to September 9, 1988;

- C. Junior Party Fischhoff conceived of an invention of amended Count 2 of this interference no later than December 12, 1986, the date the evidence shows that David Fischhoff signed and dated Monsanto Company laboratory notebook page No. 3547889, entitled "Expansion of A+T rich Genes in Plants," and page No. 3547890, entitled "A+T rich (p.2)," each page signed December 15, 1986, as read and understood by Dannette C. Ward, with page No. 3547889 and page No. 3547890 respectively having attached thereto pages one and two of a two-page printed statement of the invention of amended Count 2 signed by David Fischhoff and dated 12/12/86;
- D. Senior Party Adang has not established that it diligently endeavored to reduce the invention of amended Count 2 to practice from a time just prior to December 12, 1986, until September 9, 1988, the filing date of Adang's U.S. Application 07/242,482, now abandoned; and
- E. Senior Party Adang has not established that it conceived of the invention of amended Count 2 of this interference before December 12, 1986.

Based on the above, we conclude that (1) Junior Party
Fischhoff is entitled to priority of invention for amended
Count 2 with respect to Senior Party Adang and Junior Party
Barton; (2) Senior Party Adang is not entitled to a patent for

Claims 1-12 of U.S. Patent 5,380,831, which issued January 10, 1995; and (3) Junior Party Barton is not entitled to a patent for Claims 1-4, 7, and 15-22 of U.S. Application 07/827,906, filed January 30, 1992.

Furthermore, the findings and conclusions in Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d 1356, 59 USPQ2d 1930 (Fed. Cir. 2001): (1) relate to the patentability of Claims 7-9 and 12 of Monsanto's non-involved U.S. Patent 5,500,365 under 35 U.S.C. § 102(g) in light of Barton's evidence of prior invention thereof; (2) do not support a conclusion that the patentability of Claims 3, 5, and 39-40 of Fischhoff's presently involved U.S. Application 08/434,105, filed May 3, 1995, which stand designated as corresponding to amended Count 2 of this interference, should be rejected under 35 U.S.C. § 102(g); and (3) do not support a haphazard request for Barton to disclose all information detrimental to the patentability of Fischhoff's claims under 35 U.S.C. § 102(g).

2. <u>Background</u>

September 26, 1983 - Michael J. Adang and John D. Kemp filed U.S. Application 06/535,354, entitled "Insect Resistant Plants" (assignment to Agrigenetics Research Associates Ltd. recorded September 20, 1983; assignment to Lubrizol Genetics Inc. recorded May 29, 1986), now abandoned.

April 4, 1986 - Michael J. Adang and John D. Kemp filed U.S. Application 06/848,733, entitled "Insect Resistant Plants" (assignment to Lubrizol Genetics Inc. recorded June 25, 1986), now abandoned, as a continuation-in-part of U.S. Application 06/535,354, filed September 26, 1983.

September 9, 1988 - Michael J. Adang, Thomas A. Rocheleau, Donald J. Merlo, and Elizabeth E. Murray filed U.S. Application 07/242,482, entitled "Synthetic Insecticidal Crystal Protein Gene" (assignment to Lubrizol Genetics Inc. recorded October 24, 1988), now abandoned, as a continuation-in-part of U.S. Application 06/848,733, filed April 4, 1986.

February 24, 1989 - David A. Fischhoff and Frederick J.

Perlak filed U.S. Application 07/315,355, entitled "Synthetic

Plant Genes And Method For Preparation" (assignment to Monsanto

Company recorded February 24, 1989), now abandoned.

August 7, 1989 - Kenneth A. Barton and Michael J. Miller filed U.S. Application 07/390,561, entitled "Expression of Genes In Plants" (assignment to Agracetus, Inc. recorded August 7, 1989; assignment to Monsanto Company recorded October 15, 1996), now abandoned.

February 12, 1990 - David A. Fischhoff and Frederick J.
Perlak filed U.S. Application 07/476,661, entitled "Synthetic
Plant Genes And Method For Preparation" (assignment to Monsanto

Company recorded February 12, 1990), now abandoned, as a continuation-in-part of U.S. Application 07/315,355, filed February 24, 1989.

January 28, 1992 - Michael J. Adang, Thomas A Rocheleau,
Donald J. Merlo, and Elizabeth E. Murray filed U.S. Application
07/827,844, entitled "Synthetic Insecticidal Crystal Protein
Gene" (assignment to Mycogen Plant Science, Inc., recorded
April 1, 1993), now abandoned, as a continuation-in-part of
U.S. Application 07/242,482, filed September 9, 1988.

January 30, 1992 - Kenneth A. Barton and Michael J. Miller filed involved U.S. Application 07/827,906, entitled "Improved Expression of Genes In Plants" (assignment to Monsanto Company recorded October 15, 1996; assignment to Monsanto Technology LLC recorded June 13, 2001), as a continuation of U.S. Application 07/390,561, filed August 7, 1989.

October 9, 1992 - David A. Fischhoff and Frederick J. Perlak filed U.S. Application 07/959,506, entitled "Synthetic Plant Genes" (assignment to Monsanto Technology LLC recorded June 13, 2001), as a continuation of U.S. Application 07/476,661, filed February 12, 1990.

May 3, 1993 - Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo, and Elizabeth E. Murray filed U.S. Application 08/057,191, entitled "Synthetic Insecticidal Crystal Protein

Gene" (assignment to Mycogen Plant Science, Inc., recorded April 1, 1993), as a continuation of U.S. Application 07/827,844, filed January 28, 1992.

January 6, 1995 - Michael J. Adang, Thomas A Rocheleau,
Donald J. Merlo, and Elizabeth E. Murray filed U.S. Application
08/369,839, entitled "Synthetic Insecticidal Crystal Protein
Gene," as a division of 08/057,191, filed May 3, 1993.

January 6, 1995 - Michael J. Adang, Thomas A Rocheleau,
Donald J. Merlo, and Elizabeth E. Murray filed U.S. Application
08/369,835, entitled "Synthetic Insecticidal Crystal Protein
Gene" (assignment to Mycogen Plant Science, Inc., recorded
April 1, 1993), as a continuation-in-part of 08/057,191, filed
May 3, 1993.

January 10, 1995 - involved U.S. Patent 5,380,831 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo, and Elizabeth E. Murray, U.S. Application 08/057,191, filed May 3, 1993.

May 3, 1995 - David A. Fischhoff and Frederick J. Perlak, filed involved U.S. Application 08/434,105 entitled "Synthetic Plant Genes And Method For Preparation" (assignment to Monsanto Technology LLC recorded June 13, 2001), as a divisional of U.S. Application 07/959,506, filed October 9, 1992.

May 19, 1996 - U.S. Patent 5,500,365 issued from David A.

Fischhoff and Frederick J. Perlak, U.S. Application 07/959,506, filed October 9, 1992.

August 29, 1996 - Michael J. Adang and Elizabeth E. Murray filed U.S. Application 08/705,438, entitled "Synthetic Insecticidal Crystal Protein Gene Having A Modified Frequency Of Codon Usage" (assigned to Mycogen Plant Science, Inc.), as a divisional of U.S. Application 08/369,835, filed January 6, 1995.

August 29, 1996 - Michael J. Adang and Elizabeth E. Murray filed U.S. Application 08/704,966, entitled "Transgenic Plants Comprising Synthetic Insecticidal Crystal Protein Gene Having A Modified Frequency Of Codon Usage" (assigned to Mycogen Plant Science, Inc.), as a division of U.S. Application 08/369,839, filed January 6, 1995.

October 22, 1996 - U.S. Patent 5,567,600 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo, and Elizabeth E. Murray, U.S. Application 08/369,835, filed June 6, 1995, including a disclaimer of the terminal portion of the patent extending beyond the expiration date of Adang's involved U.S. Patent 5,380,831.

October 22, 1996 - U.S. Patent 5,567,862 issued from Michael J. Adang, Thomas A Rocheleau, Donald J. Merlo, and Elizabeth E. Murray, U.S. Application 08/369,839, filed June 6, 1995.

November 7, 1996 - Interference 103,781 was initially declared essentially as follows (Paper No. 2):

JUNIOR PARTY APPLICATION

Named Inventors: Kenneth A. Barton and Michael J. Miller

Application: Application 07/827,906, filed

January 30, 1992

Title: Improved Expression of Genes in Plants

Assignee: None (assignment to Monsanto Company

recorded October 15, 1996; assignment to Monsanto Technology LLC recorded

June 13, 2001)

Accorded benefit for the purpose of

priority of: Application 07/390,561, filed August 7,

1989

JUNIOR PARTY APPLICATION

Named Inventors: David A. Fischhoff and Frederick J.

Perlak

Application: Application 08/434,105, filed May 3,

1995

Title: Synthetic Plant Genes and Method for

Preparation

Assignee: None (assignment to Monsanto Technology

LLC recorded June 13, 2001)

Accorded benefit for the purpose of

priority of:

Application 07/959,506, filed October 9, 1992, now U.S. Patent 5,500,365, issued

March 3, 1996; Application 07/476,661, filed February 12, 1990, now abandoned;

and Application 07/315,355, filed February 24, 1989, now abandoned

SENIOR PARTY PATENT

Named Inventors: Michael J. Adang, Thomas A. Rocheleau,

Donald J. Merlo, and Elizabeth E. Murray

Application: Application 08/057,191, filed May 3,

1993, now U.S. Patent 5,380,831, issued

January 10, 1995

Title: Synthetic Insecticidal Crystal Protein

Gene

Assignee: Mycogen Plant Science, Inc. (Paper

No. 13)

Accorded benefit for the purpose of

priority of:

Applications 07/827,844, filed January 28, 1992, now abandoned, and Application 07/242,482, filed September 9, 1988, now abandoned

Count 1

A method of designing a synthetic <u>Bacillus</u> thuringiensis gene to be more highly expressed in plants, comprising the steps of:

- a) analyzing the coding sequence of a gene derived from <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, or
- b) analyzing the coding sequence of a gene derived from <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence.

The claims of the parties which were designated to correspond to this count were:

Barton et al.: Claims 1-4, 7, and 15-22

Fischhoff et al.: Claims 3, 5, and 39-43

Adang et al.: Claims 1-14.

December 12, 1996 - An administrative patent judge (APJ) entered an Order to Show Cause stating (Paper No. 11, pp. 1-2, bridging para.):

In view of the common ownership by Monsanto Company of the Barton application and the Fischhoff application, the junior party Barton is ordered to show cause why judgment should not be entered against him within 30 days from the date of this order. Monsanto Company, as the assignee of both Barton and Fischhoff, may name the prior inventor in response to this order. Cf. M.P.E.P. 2302.

January 17, 1997 - The APJ ordered Monsanto Company "to name the prior inventor of count 1 . . . In the event Monsanto makes no election, judgment will be entered against junior party Barton" (Paper No. 29, p. 3).

February 3, 1997 - Junior Party Barton et al. (hereafter Barton) petitioned the Commissioner under 37 CFR § 1.644(a)(1) to reverse or postpone the APJ's January 17, 1997 order (Paper No. 35).

March 26, 1997 - Barton's February 3, 1997, petition was denied (Paper No. 38).

June 19, 1997 - The Board of Patent Appeals and Interferences (Board) entered the following judgment (Paper No. 53):

Whereas Monsanto, the common assignee of the Barton et al. and Fischhoff et al. applications has named the party Fischhoff et al. as the prior inventor of count 1, pursuant to 37 CFR 1.602(a) and 1.610(e) judgement is hereby entered against Barton et al. as to the subject matter of count 1. Accordingly, Kenneth A. Barton and Michael J. Miller are not entitled to a patent containing Claims 1-4, 7, and 15-22 corresponding to count 1. The interference will continue as Fischhoff et al. v. Adang et al.

June 27, 1997 - Barton filed notice under 35 U.S.C. §§ 141 and 142 of appeal to the U.S. Court of Appeals for the Federal Circuit from the judgment of the Board of Patent Appeals and Interferences entered June 17, 1997 (Paper No. 55).

February 5, 1998 - The U.S. District Court for the District of Delaware entered a judgment (Mycogen Plant Science, Inc. v. Monsanto Co., No. 96-505 (D. Del. Feb. 5, 1998)) in an action brought by Mycogen Plant Science, Inc., and Agrigenetics Inc. against Monsanto Co., DeKalb Genetics Corp., and Delta and Pine Land Co. for infringement of two Mycogen patents (Adang et al., U.S. Patent 5,567,862, entitled "Synthetic Insecticidal Crystal Protein Gene," issued October 22, 1996, from U.S. Application 08/369,839, filed January 6, 1995; and Adang et al., U.S. Patent 5,567,600, entitled "Synthetic Insecticidal Crystal Protein Gene," issued October 22, 1996, from U.S. Application 08/369,835, filed January 6, 1995). A jury rendered a verdict that (1) defendants' products did not literally infringe any of the contested claims of Mycogen's patents, and (2) all of the

Contested claims of Mycogen's patents are invalid because

Monsanto invented the subject matter thereof before the priority

dates of Mycogen's patents. See the <u>Procedural History</u> in

Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316,

1320-1321, 58 USPQ2d 1030, 1033-1034 (Fed. Cir. 2001) (Paper

No. 125).

December 9, 1998 - The Court of Appeals for the Federal Circuit reversed the Board's June 19, 1997, judgment and remanded (Paper No. 124). Barton v. Adang, 162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998) (Paper No. 118, Exhibit A).

September 8, 1999 - The U.S. District Court for the District of Delaware entered a revised order (Paper No. 125, Exh. H) and ruling on post-trial motions (Paper No. 125, Exh. I) (Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F.2d 199 (D. Del. 1999)).

See Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1321, 58 USPQ2d at 1034 (Paper No. 146):

The district court granted Monsanto's motion for JMOL holding that the claims of the '600 and '862 patents were invalid for lack of enablement pursuant to 35 U.S.C. § 112.

September 8, 1999 - The U.S. District Court for the District of Delaware entered a final judgment (Monsanto Co. v. Mycogen

Plant Science, Inc., No. 96-133-RMN (D. Del. Sept. 8, 1999)) in an action brought by Monsanto Co. against Mycogen for infringement of Claims 7-9 and 12 of Monsanto's U.S. Patent

5,500,365 (Fischhoff et al., U.S. 5,500,365, issued Mar. 19, 1996, assigned to Monsanto Company). Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d 1356, 1359-61, 59 USPQ2d 1930, 1931-32 (Fed. Cir. 2001).

November 10, 1999 - In an action brought by Mycogen Plant Science, Inc. and Agrigenetics Inc. against Monsanto Company for infringement of plaintiff's patent (Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, from U.S. Application 08/057,191, filed May 3, 1993), the U.S. District Court for the Southern District of California entered an order (Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A) granting defendant's motion for summary judgment that Claims 1-12 of Mycogen's '831 patent are invalid under 35 U.S.C. § 102(g) and/or § 103 because Monsanto invented the subject matter thereof before Mycogen, as determined by the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp. 2d 199 (D. Del. 1999), affirmed in Mycogen Plant Sci., Inc. v. Monsanto Inc., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), and denied defendant's motion for summary judgment that the contested claims of Mycogen's '831 patent are invalid for noncompliance with the enablement requirement of the first paragraph of 35 U.S.C. § 112 as moot (Paper No. 127, Exh. A).

January 18, 2000 - U.S. Patent 6,015,891 issued from Adang et al., U.S. Application 08/705,438, filed August 29, 1996, subject to disclaimers of its term extending beyond the statutory expiration dates of Adang et al., U.S. Patent 5,567,600, issued October 22, 1996, and Adang et al., U.S. Patent 5,380,831, issued January 10, 1995.

January 18, 2000 - U.S. Patent 6,013,523 issued from Adang et al., U.S. Application 08/704,966, filed August 29, 1996, subject to a disclaimer of its term extending beyond the

The owner of 100% interest in the instant application, Mycogen Plant Science, Inc., hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173 for U.S. Patent No . . issued on . . .

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of U.S. Patent No . . . in the event that any of the . . . patents: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term.

But for the respective U.S. Patents identified in the terminal disclaimers entered as Paper No. 23 in U.S. Patent 6,015,891 and Paper No. 25 in U.S. Patent 6,013,523, both disclaimers read:

statutory expiration date of Adang et al., U.S. Patent 5,567,862, issued October 22, 1996.

March 12, 2001 - On appeal from the decision of the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp.2d 199 (D. Del. 1999), the U.S. Court of Appeals for the Federal Circuit:

. . . affirm[ed] the verdict of noninfringement based on patent invalidity due to prior invention pursuant to 35 U.S.C. \$ 102(g). This makes it unnecessary to address the finding of lack of enablement pursuant to 35 U.S.C. \$ 112.

Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1320,
58 USPQ2d at 1033 (Paper No. 146).

May 30, 2001 - On appeal from the decision of the U.S.

District Court for the Southern District of California in Mycogen

Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal.

Nov. 10, 1999) (Paper No. 127, Exh. A), the U.S. Court of Appeals

for the Federal Circuit affirmed-in-part, reversed-in-part, and

remanded. Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d

1306, 1309-1310, 58 USPQ2d 1891, 1892-1893 (Fed. Cir. 2001).

The Federal Circuit concluded at 1309, 58 USPQ2d at 1893, that:

. . . the district court improperly resolved disputed questions of material fact pertaining to the issue of prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in

the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding.

Id. at 1310, 58 USPQ2d at 1894, the Federal Circuit explained:

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention [claimed in the Mycogen's '831 patent] to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen was the first to conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

August 16, 2001 - On appeal from the decision of the U.S.

District Court for the District of Delaware in Monsanto Co. v.

Mycogen Plant Science, Inc., No. 96-133-RMN (D. Del. Sept. 8,
1999), the U.S. Court of Appeals for the Federal Circuit
affirmed. Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d
1356, 1359, 59 USPQ2d 1930, 1931 (Fed. Cir. 2001). At 1360,
59 USPQ2d at 1932, the Federal Circuit said, "Claims 7-9 and 12
are at issue . . ." Claims 7-9 and 12 are drawn to modified
chimeric genes, and plants transformed by modified chimeric
genes, comprising a structural coding sequence modified to
contain "at least one fewer sequence selected from the group
consisting of a AACCAA and an AATTAA sequence." Monsanto Co. v.

Mycogen Plant Science, Inc., 261 F.3d at 1360-61, 59 USPQ2d

at 1932. Claims 4-6 and 11 of U.S. Patent 5,500,365, which were not at issue, are directed to modified chimeric genes, and plants transformed by modified chimeric genes, comprising a structural coding sequence modified to contain "at least one fewer sequence selected from the group consisting of plant polyadenylation sequences and an ATTTA sequence." Columns 45-47 of Fischhoff et al, U.S. Patent 5,500,365.

September 4, 2002 - An APJ entered a Decision and Order On Preliminary and Miscellaneous Motions and Requests (Paper No. 148):

denying Adang's Preliminary Motion 1 (Paper No. 45) under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by substituting its Proposed Count 2 for existing Count 1;

dismissing Adang's Preliminary Motion 2 (Paper No. 46) under 37 CFR § 1.633(f) for benefit of the January 28, 1992, filing date of U.S. Application 07/827,844, and the September 9, 1988, filing date of U.S. Application 07/242,482, for its Proposed Count 2;

denying Adang's Contingent Preliminary Motion 3 (Paper No. 47) under 37 CFR § 1.633(a) for judgment that Claims 3, 5, and 39-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, designated as corresponding to the interference count, are unpatentable under 35 U.S.C. § 102(g)

over at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count, or under 35 U.S.C. § 103 in view of prior art including at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count. Adang's motion had presumed that, as between Fischhoff and Barton, Barton had been determined to be, or Monsanto Technology LLC (Monsanto), the assignee of Fischhoff's and Barton's involved applications, had designated Barton as, first to invent the subject matter defined by Count 1.

denying Adang's contingent request (Paper No. 47) for permission to seek deposition and documentary discovery relevant to Monsanto's presumed determination and/or election, as between Fischhoff and Barton, of Barton as first to invent the subject matter defined by the count;

dismissing Fischhoff's request (Paper No. 78) that the APJ exercise its discretion under 37 CFR § 1.642 to add commonly assigned Adang et al., U.S. Patent 5,567,600 (Fischhoff Exhibit 37 (FX 37)), issued October 22, 1996, to this interference, designate all twenty-four claims thereof as corresponding to the count, and set an additional preliminary motion period for the parties to file motions relative to the newly added patent;

exercise his discretion under 37 CFR § 1.642 to add commonly assigned Adang et al., U.S. Patent 5,567,862 (FX 3), issued October 22, 1996, to this interference, designate all twenty-four claims thereof as corresponding to the count, and set an additional preliminary motion period for the parties to file motions relative to the newly added patent;

denying Fischhoff's Preliminary Motion 3 (Paper No. 80) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 112, second paragraph;

denying Fischhoff's Preliminary Motion 4 (Paper No. 81) under 37 CFR § 1.633(c)(1) to redefine the subject matter of this interference by substituting any one of Fischhoff's Proposed Counts 2, 3 and 4 for original Count 1;

deferring to final hearing Fischhoff's Preliminary Motion 5 (Paper No. 82) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 112, first paragraph (enablement requirement);

granting Adang's motion under 37 CFR § 1.635 (Paper No. 116) for an order implementing the decision in Barton v. Adang,

162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998) (Paper No. 118, Exhibit A);

denying Fischhoff's Preliminary Motion 6 (Paper No. 83) under 37 CFR § 1.633(c)(2) to redefine the subject matter of the interference by adding proposed Claims 44 and 45 to Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995 (Paper No. 84), and designating the new claims as corresponding to the count;

deferring to final hearing Fischhoff's Preliminary Motion 7 (Paper No. 85) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are unpatentable under 35 U.S.C. § 102 or § 103;

dismissing Fischhoff's Preliminary Motion 8 (Paper No. 86) under 37 CFR § 1.633(f) to be accorded benefit of the October 9, 1992, filing date of Fischhoff's U.S. Application 07/959,506; the February 12, 1990, filing date of Fischhoff's U.S. Application 07/476,661; and the February 24, 1989, filing date of U.S. Application 07/315,355, for Fischhoff's Proposed Counts 2, 3, and 4 (Fischhoff's Preliminary Motion 4, Paper No. 81);

denying Fischhoff's Preliminary Motion 9 (Paper No. 87) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, are

unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement);

deferring to final hearing Fischhoff's Preliminary Motion No. 10 (Paper No. 88) under 37 CFR § 1.633(c)(4) to redefine the subject matter of the interference by designating (1) Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and (2) Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, as not corresponding to the count;

dismissing Fischhoff's Preliminary Motion 11 (Paper No. 89) under 37 CFR § 1.633(c)(2), contingent on granting Fischhoff's Second 37 CFR § 642 Request (Paper No. 79), to redefine the subject matter of the interference by adding proposed Claim 46 to Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995 (Paper No. 90), and designating the new claim as corresponding to the count;

dismissing Fischhoff's Preliminary Motion 12 (Paper No. 60) under 37 CFR § 1.633(f), contingent upon the granting of Adang's Preliminary Motion 1 (Paper No. 45), for benefit of the October 9, 1992, filing date of Fischhoff's U.S. Application 07/959,506, the February 12, 1990, filing date of Fischhoff's U.S. Application 07/476,661, and the February 25, 1989, filing

date of Fischhoff's U.S. Application 07/315,355, for subject matter defined by Adang's Proposed Substitute Count 2;

denying Fischhoff request under 37 CFR § 1.641(a) (Paper No. 110) that the APJ exercise its discretion and notify the parties that Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995, appear to be unpatentable under 35 U.S.C. § 112, first paragraph (best mode requirement), and set a time period for the parties to take testimony and present related evidence and argument;

dismissing Fischhoff's motion under 37 CFR § 1.635 (Paper No. 118) for an order temporarily staying the interference proceeding under 37 CFR § 1.645(d) in anticipation of an impending decision of the U.S. District Court for the Southern District of California "on a motion for summary judgment that the claims of . . . Adang's . . . U.S. Patent No. 5,380,831 are invalid under 35 U.S.C. § 102(g) because of prior invention by . . . Fischhoff . . ." (Paper No. 118, p. 2, para. I);

dismissing Fischhoff's motion under 37 CFR § 1.635 (Paper No. 127) for an order temporarily staying the interference proceedings under 37 CFR § 1.645(d) pending a decision on appeal to the Federal Circuit of a decision of the U.S. District Court for the Southern District of California on Monsanto's motion for summary judgment that claims of Adang's U.S. Patent 5,380,831 are

invalid under 35 U.S.C. § 102(g) over the prior invention of Fischhoff (Paper No. 127, p. 2, para. I); and ordering:

(1) Interference 103,781 "redeclared as <u>Barton</u>

(U.S. Application 07/827,906) or <u>Fischhoff</u> (U.S. Application

08/434,105) v. Adang (U.S. Patent 5,380,831)" (Paper No. 148)

with the following new Count 2:

Count 2

Any one of Claims 1-4, 7, and 15-22 of Barton et al.'s Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 3, 5, and 39-43 of Fischhoff et al.'s Application 08/434,105, filed May 3, 1995;

- or -

Any one of Claims 1-14 of Adang et al.'s
U.S. Patent 5,380,831, which issued January 10, 1995,
from U.S. Application 08/057,191, filed May 3, 1993.
with Barton's Claims 1-4, 7, and 15-22; Fischhoff's Claims 3, 5,
and 39-43; and Adang's Claims 1-14 designated as corresponding to
new Count 2;

(2) the parties to consider the relationship of the subject matter defined by Count 2 of this interference to subject matter claimed in Mycogen's U.S. Patents 6,013,523 and 6,015,891 and comment thereon;

- (3) the parties to specify whether the time for filing preliminary motions should be extended;
- (4) the parties to specify what additional preliminary motions, if any, and supporting evidence, if any, need be filed in this newly declared interference;
- (5) the parties to explain why the additional preliminary motions and supporting evidence specified are necessary to, and should be filed in, this interference proceeding, and
- (6) the parties to recommend time periods for filing the specified additional preliminary motions, supporting evidence, oppositions, replies, motions to suppress evidence, etc.

November 26, 2002 - Adang filed a REQUEST FOR RECONSIDERATION and RESPONSES RE: THE DECISION ON MOTIONS AND REQUEST (Paper No. 154):

I. alternatively asking the Board to:

require Monsanto to elect the first to invent the subject matter defined by Count 2 as between Barton and Fischhoff;

remand the Barton and Fischhoff applications to a primary examiner to require identification of Fischhoff or Barton as the first to invent the subject matter defined by Count 2 under 37 CFR § 1.78(c); or

declare separate interferences, <u>i.e.</u>, Fischhoff v. Adang and Barton v. Adang;

II. asking the Board for leave to file preliminary motions under 37 CFR § 1.633(a) for judgment that:

Barton is not entitled to a patent containing Barton's claims designated as corresponding to Count 2 in view of Monsanto's alleged violation of 37 CFR § 1.56; and

Fischhoff is not entitled to a patent containing Fischhoff's claims designated as corresponding to Count 2 in view of Monsanto's alleged violation of 37 CFR § 1.56;

- III. asking the Board for leave to file a miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR § 1.687(c) relating to Monsanto's alleged violation of 37 CFR § 1.56;
- IV. asking the Board for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Barton's Claims 21 and 22 are unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement);
- V. asking the Board for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Fischhoff's Claim 40 is unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement);
- VI. asking the Board for leave to file a preliminary motion under 37 CFR \$ 1.633(c)(1) to redefine the interfering

subject matter by excluding Adang's Claims 2, 3, 5-7, 9, 10, 13, and 14 from Count 2;

VII. asking the Board for leave to file a renewed or amended miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR § 1.687(c) relating to derivation of invention; and

VIII. asking the Board to refrain from adding Mycogen's U.S. Patents 6,013,523 and 6,015,891 to this interference.

November 29, 2002 - Fischhoff and Barton filed Joint Comments Requesting Addition of Adang Patents to Interference (Paper No. 157):

- I. asking the Board to exercise discretion under $37 \ \text{CFR} \ \$ \ 1.642$ and:
- a. add Adang et al., U.S. Patent 6,015,891 (Adang '891), issued January 18, 2000, to this interference, and designate Claims 1-6 thereof as corresponding to Count 2;
- b. add Adang et al., U.S. Patent 6,013,523 (Adang `523), issued January 11, 2000, to this interference, and designate Claims 1-4 thereof as corresponding to Count 2; and
- c. grant Fischhoff and/or Barton leave to brief for final hearing issues relating to the patentability of Claims 1-6 of Adang's '891 patent and Claims 1-4 of Adang's '523

patent under 35 U.S.C. §§ 102, 103, and 112, which had been raised in preliminary motions with respect to claims of Adang's involved U.S. Patent 5,380,831, issued January 10, 1995, designated as corresponding to Count 2 and deferred to final hearing (Paper No. 148); and

II. expressing no desire to file any new preliminary motions.

December 5, 2002 - Adang filed a Request to Strike Monsanto Motion or Set Period for Response Thereto (Paper No. 160) asking the Board alternatively to (1) strike Fischhoff and Barton's Joint Comments Requesting Addition of Adang Patents to Interference (Paper No. 157); or (2) set a period for Adang to respond to Fischhoff's and Barton's Joint Comments Requesting Addition of Adang Patents to Interference (Paper No. 157).

December 9, 2002 - Fischhoff and Barton filed Joint Comments
Concerning Adang's Request for Reconsideration and Responses Re:
the Decision on Motions and Requests (Paper No. 161) asking the
Board to (1) dismiss Adang's request for reconsideration;
(2) deny Adang's requests for leave to file every new preliminary
motion it proposes to file but for Adang's request for leave to
file a motion under 37 CFR § 1.633(a) to declare Barton's
Claims 21 and 22 unpatentable under 35 U.S.C. § 112, first
paragraph (written description requirement); (3) set a time

period for Barton to file its preliminary statement; and

(4) add Adang's U.S. Patents 6,015,891 and 6,013,523 to this interference;

December 16, 2002 - Adang filed Observations Regarding

Monsanto's Joint Comments (Paper No. 162) asking the Board to (1)

strike Fischhoff's and Barton's Joint Comments Concerning Adang's

Request for Reconsideration and Responses Re: the Decision on

Motions and Requests (Paper No. 161); and (2) set a time period

for Adang to file a supplemental preliminary statement.

May 20, 2003 - An APJ entered a DECISION AND ORDER ON PROPOSED PRELIMINARY AND MISCELLANEOUS MOTIONS AND REQUESTS (Paper No. 164):

denying Adang's request to require Monsanto to designate Fischhoff or Barton as first to invent the subject matter of Count 2 (Paper No. 154);

denying Adang's requests for leave to file preliminary motions under 37 CFR § 1.633(a) for judgment that all Fischhoff and Barton claims designated as corresponding to Count 2 are unpatentable due to common assignee Monsanto's purported violations of 37 CFR § 1.56 (Paper No. 154);

denying Adang's request for leave to file a miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR

§ 1.687(c) relating to Monsanto's purported violation of 37 CFR § 1.56 (Paper No. 154);

granting Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Claims 21 and 22 of Barton's Application 07/827,906, filed January 30, 1992, are unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement) (Paper No. 154);

denying Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Claim 40 of Fischhoff's Application 08/827,906, filed May 3, 1995, is unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement) (Paper No. 154);

denying Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by excluding Claims 2, 3, 5-7, 9, 10, 13 and 14 of Adang's U.S. Patent 5,380,831 from this interference (Paper No. 154);

denying Adang's request for leave to renew or amend a motion under 37 CFR § 1.635 said to have been filed earlier "for discovery under 37 CFR § 1.687(c) Re: Derivation of Invention" (Paper No. 154); and

dismissing Fischhoff's invitation to add Mycogen's U.S. Patents 6,013,523 and 6,015,891 to this interference (Paper No. 157).

June 3, 2003 - Adang filed a Request For Reconsideration

(Paper No. 166) of the APJ's Decision And Order On Proposed

Preliminary And Miscellaneous Motions And Requests, dated May 20,

2003 (Paper No. 164).

June 5, 2003 - An APJ entered a Decision On Adang's Request For Reconsideration (Paper No. 168), granting-in-part and denying-in-part Adang's Request For Reconsideration (Paper No. 166).

June 5, 2003 - Fischhoff and Barton filed a Joint Request For Reconsideration Of Decision To Exclude Adams Patents From Interference (Paper No. 169).

June 9, 2003 - An APJ denied Fischhoff and Barton's June 5, 2003, joint request (Paper No. 170).

June 17, 2003 - Adang filed a Request For Authorization To File Expanded Motion under 37 CFR § 1.633(a) for judgement that all of Barton's claims are unpatentable under 35 U.S.C. § 112, first paragraph (written description and enablement requirements) (Paper No. 171).

June 17, 2003 - Barton, Fischhoff, and Adang filed a Joint Request For Modified Schedule (Paper No. 172).

June 18, 2003 - An APJ denied Adang's June 17, 2003, Request For Authorization To File Expanded Motion under 37 CFR § 1.633(a) (Paper No. 173).

June 18, 2003 - An APJ denied Barton, Fischhoff, and Adang's Joint Request For Modified Schedule (Paper No. 174).

July 18, 2003 - Fischhoff filed its Supplemental Preliminary Statement (Paper No. 175).

July 18, 2003 - Fischhoff filed Monsanto Election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, <u>vis-a-vis</u> the Junior Party Barton et al., the subject matter defined by Count 2" and statement of intent not to submit "any further documents in this interference on behalf of the Junior Party Barton" (Paper No. 182).

July 21, 2003 - Adang filed a Request For Immediate Entry Of Judgment Against Barton (Paper No. 198).

July 22, 2003 - Adang filed a Request For Authorization
To Address The Unpatentability Of Fischhoff's Claims [under
35 U.S.C. § 102(g) in view of Barton's invention of subject
matter within the scope of Count 2] And To Obtain Related
Discovery (Paper No. 199).

July 28, 2003 - Adang filed Adang's Supplemental Preliminary Statement (Paper No. 208).

July 29, 2003 - An APJ entered a Decision On Adang's Requests For Immediate Entry Of Judgment Against Barton And Authorization To Address The Unpatentability Of Fischhoff's Claims And To Obtain Related Discovery (Paper No. 212) denying Adang's July 21, 2003, and July 22, 2003, requests.

August 6, 2003 - Fischhoff filed Fischhoff Rule 635 Motion For Order Striking The "Notice of Adang's Case-In-Rebuttal" Or, Alternatively, Contingent Motion For Suppression Of The Evidence Identified Therein (Paper No. 215).

August 8, 2003 - Adang filed Adang's Notice Under 37 CFR § 1.640(b) for review of the following at final hearing (Paper No. 219):

- 1. Issues relating to priority of invention between the parties to this interference;
- September 4, 2002, Order and Decision on Motions (Paper No. 148);
- 3. May 20, 2003, Order and Decision on Motions;
- 4. June 18, 2003, Decision on Adang's Request for Reconsideration;
- 5. July 29, 2003, Decision on Adang's Requests for Immediate Entry Of Judgment Against Barton and For Authorization to Address the Unpatentability of Fischhoff's Claims and to Obtain Related Discovery (Paper No. 212); and
- 6. Any decisions or matters raised <u>sua sponte</u> with respect to Adang's Case-in-Rebuttal which are entered after the filing of this notice.

August 8, 2003 - Fischhoff filed Fischhoff Submission

Pursuant To 37 CFR § 1.640(b) for review of the following at

final hearing (Paper No. 220):

- A. Whether Fischhoff's Claims 41-43 are separately patentable from the interference count and should not be designated as corresponding to the count (Fischhoff's Preliminary Motion 10 (Paper No. 88) and Decision deferring judgment on Fischhoff's Preliminary Motion 10 until final hearing (Paper No. 148); and
- B. Priority of invention of the subject matter of the interference count.

August 12, 2003 - An APJ entered an Order deferring judgment on Fischhoff's August 6, 2003, Rule 635 motion or contingent motion to final hearing (Paper No. 217).

August 18, 2003 - Fischhoff filed Fischhoff Priority Brief For Final Hearing (Paper No. 243).

August 18, 2003 - Fischhoff filed Fischhoff Motions Brief For Final Hearing On Deferred Fischhoff Motion 10 (Paper No. 224).

August 18, 2003 - Adang filed Senior Party Adang's Brief At Final Hearing (Paper No. 223).

August 28, 2003 - Adang filed Adang's Reply To Fischhoff's Motions Brief (Paper No. 245).

August 28, 2003 - Adang filed Adang's Reply To Fischhoff's Priority Brief (Paper No. 246).

August 28, 2003 - Fischhoff filed Fischhoff's Reply Brief For Final Hearing (Paper No. 247).

August 28, 2003 - Fischhoff filed Fischhoff Motion To Suppress Evidence (Paper No. 248).

September 5, 2003 - Adang filed its Opposition To Fischhoff Motion To Suppress Evidence (Paper No. 251).

September 12, 2003 - Fischhoff filed Fischhoff Reply In Support Of Its Motion To Suppress Evidence (Paper No. 252).

September 26, 2003 - Final Hearing for Interference 103,781.

3. Fischhoff's Preliminary Motion 10

Fischhoff's Preliminary Motion 10 under 37 CFR § 1.633(c)(4) (Paper No. 88) asked the Board to designate Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, as not corresponding to the interference count, and to amend Count 2 to exclude its reference to those claims. The motion was deferred to final hearing (Paper No. 148). Adang originally opposed the motion (Paper No. 70). However, Adang no longer opposes Fischhoff's Preliminary Motion 10 (Paper No. 245, p. 1, para. 3). Whether Adang opposes Fischhoff's motion or not, "[the] party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion." 37 CFR § 1.637(a).

37 CFR \S 1.637(c)(4) reads (emphasis added):

A preliminary motion seeking to designate an application of patent claim as not corresponding to a count shall:

(i) Identify the claim and the count.

(ii) Show that the claim does not defined [sic] the <u>same patentable invention</u> as any other claim whose designation in the notice declaring the interference as corresponding to the count the party does not dispute.

37 CFR § 1.601(n) defines "same patentable invention" as follows:

Invention "A" is the <u>same patentable invention</u> as an invention "B" when invention "A" is the same as (35 U.S.C. 102) or is obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A". Invention "A" is a <u>separate patentable invention</u> with respect to invention "B" when invention "A" is new (35 U.S.C. 102) and non-obvious (35 U.S.C. 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Fischhoff maintains that Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and Claims 13-14 of Adang's U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, are directed to separate patentable inventions from the subject matter defined by all other claims of the parties designated as corresponding to Count 2 (Paper No. 224, p. 9). Fischhoff argues that Claims 1-4, 7, 15-17, and 19-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992; Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; and Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995, all define a genus of genetic sequences which would not have described a species defined by any one of Claims 41-43 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995, or Claims 13-14 of Adang's U.S. Patent 5,380,831, within the meaning of the word

"described" in 35 U.S.C. § 102, nor rendered any species thereof obvious to a person having ordinary skill in the art at the pertinent time.

Claims 41-43 of Fischhoff's involved application and Claims 13-14 of Adang involved patent are each limited to a synthetic gene comprising a specifically identified DNA sequence. The gene of Claim 41 of Fischhoff's involved application requires the specific sequence of 1791 nucleotides identified therein (Fischhoff's Priority Brief For Final Hearing (Paper No. 243), pp. 164-166 (FPB 164-166)). The gene of Claim 42 of Fischhoff's involved application requires the specific sequence of 3567 nucleotides identified therein (FPB 166-170). The gene of Claim 43 of Fischhoff's involved application requires the specific sequence of 1905 nucleotides identified therein (FPB 166-170). The gene of Claim 13 of Adang's involved patent requires "the DNA sequence presented in Fig. 1 [of the patent], spanning nucleotides 1 through 1793 (FPB 174). The gene of Claim 14 of Adang's involved patent requires "the DNA sequence presented in Fig. 1 [of the patent], spanning nucleotides 1 through 1833" (FPB 174). We find that the prior art of record does not anticipate any of the specific genes claimed by Fischhoff or Adang.

On the other hand, the question whether a species of any one of Claims 41-43 of Fischhoff's U.S. Application 08/434,105, filed

May 3, 1995, or Claims 13-14 of Adang's U.S. Patent 5,380,831, would have been obvious in view of any other claim designated as corresponding to Count 2, with or without the combined teachings of all the prior art of record, is a question of law.

Fischhoff argues that there is no "motivation or suggestion to make the particular species from the teaching of the genus" (Paper No. 224, para. bridging pp. 10-11). We do not agree that there is no motivation or suggestion to make and use the particular species claimed by Fischhoff and by Adang. The motivation or suggestion to make and use a chemical species defined in terms of chemical structure, formula, name or properties need not be explicit. The motivation or suggestion to make and use a particular chemical species may be implicit from a prior art genus of definitive scope. For example, In re Payne, 606 F.2d 303, 203 USPQ 245 (CCPA 1979), teaches at 314, 203 USPQ at 255:

When prior art compounds essentially "bracketing" the claimed compounds in structural similarity are all known as pesticides, one of ordinary skill in the art would clearly be motivated to make those claimed compounds in searching for new pesticides.

Here, one might reasonably conclude that a person having ordinary skill in the art would have been "motivated" to make and use the particular species claimed by Fischhoff or Adang by the desire to (1) reduce the number of polyadenylation and ATTTA sequences in

well-defined native Bt genes encoding insecticidal proteins, (2) delete at least one polyadenylation sequence and at least one ATTTA sequence from well-defined native <u>Bt</u> structural sequences encoding insecticidal proteins, or (3) replace any one or more codons in well-defined native Bt structural gene sequences encoding insecticidal proteins with one or more plant-preferred codons encoding the same amino acid to effect increased expression of the Bt gene sequences in plants. However, a conclusion that the specific subject matter of any one of Fischhoff's Claims 41-43 or Adang's Claims 13-14 would have been obvious under 35 U.S.C. § 103 in view of prior art teaching including the parties' other claims designated as corresponding to Count 2 requires more than the motivation or suggestion to modify a native Bt gene sequence in any manner Fischhoff, Adang, or Barton claim to make and use a modified Bt gene sequence encoding insecticidal Bt protein for higher expression in plants. It also requires a reasonable expectation of success.

Where, as here, the evidence of record indicates that the art of expressing chimeric DNA in plants was unpredictable in practice, the collective prior art teaching must provide persons having ordinary skill in the art with sufficient direction and guidance to modify native <u>Bt</u> gene sequences encoding insecticidal <u>Bt</u> protein with a reasonable expectation that the gene sequences

so modified would be more highly expressed in plants than the corresponding unmodified native <u>Bt</u> gene sequences encoding insecticidal <u>Bt</u> protein, <u>i.e.</u>, sufficient direction and guidance to reasonably expect success. <u>In re O'Farrell</u>, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

None of Claims 1-12 of Adang's U.S. Patent 5,380,831 itself makes a prima facie case for the unpatentability of any one of Claims 13-14 of Adang's patent or Claims 41-43 of Fischhoff's involved application under 35 U.S.C. § 103. To successfully modify a native Bt gene encoding insecticidal Bt protein for enhanced expression in a plant, Adang's Claims 1-12 instruct persons having ordinary skill in the art to modify a portion of a native Bt coding sequence to yield a modified sequence which (1) "contains a greater number of codons preferred by the intended plant host than did said coding sequence", or (2) "has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed" (independent Claims 1 and 11 of Adang's U.S. Patent 5,380,831 (FX 11)). None of Adang's Claims 1-12 indicate which codons are preferred by any particular plant host to be transformed by a modified Bt coding sequence. The information required for this analysis may be found in Table 1 of Adang's patent specification which provides certain embodiments within

the broad language of Adang's Claims 1-12. Table 1 of Adang's involved patent "presents the frequency of codon usage for (A) dicot proteins, (B) Bt proteins, (C) the synthetic Btt [Bacillus thuringiensis var. tenebrionis] gene, and (D) monocot proteins" (Adang's U.S. Patent 5,380,831 (Column 18). However, Adang's Table 1 is not part of any of Adang's claims and is not otherwise prior art with regard to any species of Claims 13-14 of Adang's involved patent or Claims 41-43 of Fischhoff's involved application. Similarly, persons having ordinary skill in the art can only determine the "frequency of codon usage which more closely resembles the frequence of codon usage of the plant in which it is to be expressed", the critical phrase of a method step of Claim 11 of Adang's involved patent, by dividing the number of occurrences of each codon in highly expressed plant genes by the total number of occurrences of all codons specifying the same amino acid in the gene (Adang, U.S. Patent 5,380,831, col. 7, 1. 3-7). Again, information necessary for persons skilled in the art to perform this step is found in Table 1 of Adang's patent specification. Still, Table 1 of Adang's specification is not prior art either to Claims 13-14 Adang's involved patent or Claims 41-43 of Fischhoff's involved application. Absent prior art quidance or direction to plantpreferred codons, Claims 1-12 of Adang's involved patent would

not have rendered either Claims 13-14 of Adang's involved patent or Claims 41-43 of Fischhoff's involved application obvious to persons having ordinary skill in the art. While Monsanto's employees appear to have generated plant codon usage tables in 1984 from previously published information and those tables were available for use by Monsanto's employees at the critical time, the uncontradicted evidence of record indicates that codon usage tables were generated for internal distribution to Monsanto's employees, i.e., Monsanto's codon usage tables also are not prior art with respect to the species Fischhoff and Adang claim (MDX 1457).

However, Rule 601(n) instructs that the pertinent "prior art" for interference analysis includes not only Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995; but also, inter alia, Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; and Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992. Shaw et al. (hereafter Shaw), "A Conserved AU Sequence from the 3' Untranslated Region of GM-CSF mRNA Mediates Selective mRNA Degradation," Cell, Vol. 46, pp. 659-667 (August 29, 1986); and Wickens et al. (hereafter Wickens), "Role of the Conserved AAUAAAA Sequence: Four AAUAAAA Point Mutants Prevent Messenger RNA 3' End Formation," Science, Vol. 226, pp. 1045-1051 (November 30,

1984) (Adang Exhibit No. 121L (AX 121L)), also are prior art to the involved claims under 35 U.S.C. § 102(b). Nevertheless, it is our view that persons having ordinary skill in the art reasonably would not have been led by any one of Fischhoff's Claims 3, 5, and 39-40 or Barton's Claims 1-4, 7, and 15-22 to make and use the subject matter defined by Claims 13-14 of Adang's involved patent or Fischhoff's Claims 41-43 with a reasonable expectation that the particularly modified Bt genes would be more highly expressed in plants.

We note that Fischhoff's method Claims 3 and 5 specify removal of ATTTA sequences, yet Claims 13-14 of Adang's patent purportedly embody synthetic <u>Bt</u> genes having a greater number of codons preferred by the intended plant. While Fischhoff's method Claim 39 and synthetic gene Claim 40 do specify "a greater number of codons preferred by the intended plant", neither claim provides any specific guidance or direction for choosing plant-preferred codons or comparing frequencies of plant codon usage. Moreover, even if Fischhoff's method Claims 3 and 5 might have led persons having ordinary skill in the art generally to make and use species of modified chimeric genes more highly expressed in a chosen plant, there is no guidance or direction therein toward the particular species of Fischhoff's Claims 41-43. We

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are instructed by <u>In re Deuel</u>, 51 F.3d 1552, 1559, 34 USPQ2d 1210, 1216 (Fed. Cir. 1995):

The fact that one can conceive a general process in advance for preparing an <u>undefined</u> compound does not mean that a claimed <u>specific</u> compound was precisely envisioned and therefore obvious.

Similarly, while method Claims 1 and 7 of Barton's involved application incorporate a codon preference or usage table, they remain general methods with little or no guidance or direction toward any of the particular species of Adang's Claims 13-14 or Fischhoff's Claims 41-43. Claim 1 of Barton's involved application includes the following steps (Fischhoff's Priority Brief (Paper No. 243), p. 158 (FPB 158) (emphasis added)):

- (a) analyzing the pattern of nucleotide codon usage in native plant genes having relatively high levels of expression in plants to select from among the codons coding for the same amino acid the codons for each amino acid which are utilized preferentially by the native plant genes;
- (b) synthesizing a chimeric nucleotide coding sequence coding for the expression of the amino acid sequence of the delta-endotoxin from <u>Bacillus thuringiensis</u> with the chimeric coding sequence comprising codons differing from those in the coding sequence in <u>Bacillus thuringiensis</u> and selected from among <u>the codons determined from Figure 1 to be preferentially utilized by the native plant gene</u>

Claim 7 of Barton's involved application reads (FPB 159):

7. A method as claimed in Claim 1 wherein the codons determined to be preferentially expressed in plants disproportionately those codons which have a C or a G nucleotide in the third position in the codon in preference to an A or a T.

Figure 1 to which Barton's Claim 1 refers is a "Codon Usage In Plants Frequency Table" for use in determining plant-preferred codons. Nevertheless, the evidence of record does not show that persons having ordinary skill in the art would have been led to make and use the particular species of any one of Claims 13-14 of Adang's involved patent or Claims 41-43 of Fischhoff's involved application with a reasonable expectation of success, and certainly without a reasonable expectation of the degree of success achieved. See, inter alia, facts 121-128 and 192-196 on pages 56-58 and 78-80 of Fischhoff's priority brief (FPB 56-58 & 78-80), and the evidence of record cited in support thereof.

The issue of whether Adang's Claims 13-14 and Fischhoff's Claims 41-43 are patentable in view of the DNA molecule broadly defined by Barton's Claim 19 corresponding to Count 2 differs because Claim 19 is drawn to a genus of effective products rather than a process of making effective products as recited in Adang's Claims 1-12, Fischhoff's Claims 3, 5, and 39, and Barton's Claims 1-4, 7, and 20-22. Claim 19 of Barton's involved application reads (FPB 161):

19. A DNA molecule comprising a gene including a protein coding sequence derived from the 5' end of the gene from <u>Bacillus thuringiensis</u> encoding a delta-endotoxin natively in excess of 72 kD in size and natively toxic upon ingestio[n] by <u>Manduca sexta</u>, the gene including appropriate regulatory sequences to express the protein coding sequence so that cells of a plant hosting the gene produce delta-endotoxin protein so as to be toxic upon

ingestion by <u>Manduca sexta</u>, the protein coding sequence of the gene including a 5' region of at least 150 nucleotides in length constructed from nucleotide codons selected from those codons determined from Figure 1 to be efficiently expressed in the cells of plants, the sequence of codons being different from those in the protein coding sequence of the gene in <u>Bacillus thuringiensis</u>.

Adang and Fischhoff point to generic teachings at least as broad in scope as their broadest claims designated as corresponding to Count 2 and the same Shaw and Wickens publications in support of the respective dates each allegedly conceived of the invention of Count 2. Conception is "a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). However, "one need not necessarily meet the enablement standard of 35 U.S.C. § 112 to prove conception." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d at 1231, 32 USPQ2d at 1922. For conception, "[t]he question is not whether Burroughs Wellcome reasonably believed that the inventions would work for their intended purpose . . . but whether the inventors had formed the idea of their use for that purpose in sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice." Id. The inventor need not know that the invention will work for conception to be complete. Id. at 1228-29, 32 USPQ2d at 1919-20.

However, to establish that the inventive process Fischhoff conceived would have been obvious to persons having ordinary skill in the art in view of the same prior art teaching, the prior art would have had to have led them to reasonably expect that the synthetic genes of Claims 41-43 of Fischhoff's involved application and Claims 13-14 of Adang's involved patent would Thus, to make its case for the patentability of work. Fischhoff's Claims 41-43 over the prior art including, inter alia, Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995; Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992; Shaw; and Wickens; the prior art must have presented more than an "obvious to try" situation where, as O'Farrell instructs at 852 F.2d at 903, 7 USPQ2d at 1681 (emphasis added):

[W] hat would have been "obvious to try" would have been to . . . try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

To establish an invention's obviousness in view of prior art teaching, the collective prior art must have provided persons having ordinary skill in the art with more than "a general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the

particular form of the claimed invention or how to achieve it."

In re O'Farrell, 853 F.2d at 903, 7 USPQ2d at 1681. Unlike the requirement for conception, to establish obviousness in view of prior art teachings, the prior art must provide enough guidance and direction to have led persons having ordinary skill in the art to reasonably expect that a native Bt gene sequence encoding insecticidal protein, when modified in any manner indicated by the parties' broadest claims, Shaw, Wickens, and the preexisting knowledge in the art, would be more highly expressed in plants then the native Bt gene sequence itself.

Here, the preponderance of the evidence of record indicates that, even assuming prior knowledge of the concept of any one of Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992; Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; or Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995, claims designated as corresponding to Count 2, persons having ordinary skill in the art reasonably could not have predicted that a native Bt gene sequence modified in accordance with any of the above claims designated as corresponding to Count 2 without dispute, would be more highly expressed in a plant than the native Bt gene sequence from which it was derived, i.e., was likely to be successful. For example, David Fischhoff, himself,

would not have reasonably predicted in September of 1987 that plants would express native <u>Bt</u> gene sequences modified in accordance with his own concept more than unmodified native <u>Bt</u> gene sequences until test results showed "increased <u>Bt</u> expression in early- to mid-August 1988." <u>Mycogen Plant Sci., Inc. v.</u>

<u>Monsanto Co.</u>, 243 F.3d at 1335, 58 USPQ2d at 1045. Fischhoff testified (MR0489, p. 2014, l. 24, to p. 2015, l. 21; emphasis added):

- Q. Dr. Fischhoff, could you predict on September 8th, '87 how either of these sequences would work in plants?
- A. On September 8^{th} , '87, we had an expectation that genes designed by our methodology would work much better in plants than native Bt genes.
- Q. That was your goal. Had you ever put one of those genes into plants by September 8^{th} , `87?
- A. We had not, by September 8th, 187.
- Q. You had no data on September 8th, '87; is that right?
- A. We had no data on expression in plants.
- Q. And as a good scientist, you couldn't predict how these sequences were going to work in plants, could you?
- A. Well, certainly, our aim was and our expectation was that they would work. I don't know if you could characterize that was a prediction or not.
- Q. I understand that. I'm asking you if you could have predicted one sequence as compared to another how they would work in plants on that date?
- A. Assuming that the genes were not substantially changed in what I would have called our target regions, which we

had specified, <u>I would have predicted they would work</u> equivalently.

Moreover, David Fischhoff did not believe that native <u>Bt</u> gene sequences modified in accordance with methods claimed in Adang's patents would be more highly expressed in plants than unmodified native <u>Bt</u> gene sequences (MR0449, p. 1101, 1. 2, to p. 1102, 1. 10):

- Q. What was your reaction to finding out those patents had issued?
- A. I was really surprised even shocked to find out that those patents had issued.
- Q. Why?
- A. Really for three reasons. First of all, we looked at those patents when they issued, saw what the text described and what the claims were and compared it to our own work and, you know, we had been confident all along, Fred and I, that we had been the first to invent the synthetic Bt solution. And I was just surprised to see that the Patent Office had issued patents like this to somebody other than the two of us, to be honest.
- Q. Okay.
- A. And in addition, we had asked the Patent Office to declare what is called an interference, it's a priority contest.

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- Q. At the time you didn't believe that the claims proscribed [sic] would work; is that right?
- A. That's right. And that's the other reason I was really shocked to see these patents issue, because when I had a chance to study the claims and saw that what they really seemed to say was take out one XCG or one AATGAA from Bt gene and you get higher expression in plants, I

couldn't believe it. I had never seen anybody suggest that that could be the case. I had never heard that in scientific meetings, never seen a scientific publication and I certainly didn't believe it myself.

Rather, the evidence of record indicates that Fischhoff himself was astonished by the test results for plants transformed by native <u>Bt</u> gene sequences modified in accordance with a method encompassed by Count 2 (MR0448). The magnitude of the effect was completely unexpected.

In short, having considered the prior art as a whole, including each of Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992; Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; and Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995, all claims designated as corresponding to Count 2, we find that persons having ordinary skill in the art reasonably would not have been led to, make and use the particular Bt gene sequences of Claims 13-14 of Adang's involved patent or Claims 41-43 of Fischhoff's involved application with reasonable expectation of successfully increasing expression thereof in plants as compared to expression of the unmodified Bt gene sequence in plants. Therefore, we conclude that species Claims 13-14 of Adang's involved patent and Claims 41-43 of Fischhoff's involved application are directed to separate patentable inventions from all of the parties' other claims

designated as corresponding to Count 2 without dispute and separate patentable inventions from each other. Therefore, Fischhoff's Preliminary Motion 10 is <u>GRANTED</u>.

Accordingly, Count 2 of this interference is now amended to delete all references therein to Claims 13-14 of Adang's involved patent and Claims 41-43 of Fischhoff's involved application; and Claims 13-14 of Adang's involved patent and Claims 41-43 of Fischhoff's involved application are newly designated as not corresponding to amended Count 2. A formal order setting forth amended new Count 2 and the associated claim correspondence appears at the end of this opinion.

Since Fischhoff has not relied on the particular subject matter defined by Claims 41-43 of Fischhoff's involved application and Adang has not relied on the particular subject matter defined by Claims 13-14 of Adang's involved patent to make their respective Cases-In-Chief for priority of the invention of Count 2, we proceed to consider the parties' Cases-In-Chief with respect to Count 2 as amended to exclude the separate patentable inventions of Claims 41-43 of Fischhoff's involved application and Claims 13-14 of Adang's involved patent (hereafter Count 2).

4. Priority of Invention of Count 2

According to Senior Party Adang's Brief At Final Hearing,
Adang's Supplemental Preliminary Statement alleges that "Adang's

actual reduction to practice of the invention defined by Count 2 was not prior to the filing date of the earliest application upon which Adang is entitled to rely for benefit (<u>i.e.</u>, USSN 07/242,482, filed September 9, 1988)" (Paper No. 223, p. 43). However, Adang maintains that it first conceived of the invention of Count 2 on November 6, 1985, and exercised reasonable diligence during the period beginning prior to November 6, 1985, until constructive reduction to practice of the invention of Count 2 on September 9, 1988 (Paper No. 223, p. 43).

According to Senior Party Adang's Brief At Final Hearing, Fischhoff's Supplemental Preliminary Statement indicates that Fischhoff first conceived of the invention of Count 2 on October 30, 1986 (Paper No. 223, p. 43). However, "Fischhoff's first actual reduction to practice of the invention defined by Count 2 was on December 29, 1987" (Paper No. 223, p. 43).

Having considered all the evidence of record, the evidence clearly and convincingly shows that Fischhoff actually reduced the invention of Count 2 to practice no later than August 10, 1988, and that Fischhoff conceived of the invention of Count 2 no later than December 12, 1986. On the other hand, the preponderance of the evidence of record indicates that Adang not only did not exercise reasonable diligence during the critical period just prior to Fischhoff's latest date of conception of the

invention of Count 2 on December 12, 1986, to the September 9, 1988, filing date of Adang's Application 07/242,482, but also did not conceive of the invention of Count 2 prior to December 12, 1986, the latest date the evidence shows that Fischhoff conceived of the invention defined by Count 2.

A. Junior Party Fischhoff's Case-In-Chief For Priority

I. Fischhoff's Actual Reduction to Practice

As between Junior Party Fischhoff and Junior Party Barton, common assignee Monsanto elected Fischhoff as first to invent subject matter defined by Count 2 (Paper No. 182). Thereafter, as the first step toward establishing that it was first to invent the subject matter defined by Count 2, Fischhoff had the initial burden to prove by clear and convincing evidence (37 CFR § 1.657(c)) that it actually reduced an embodiment of Count 2 to practice before September 9, 1988, the filing date of Adang's benefit U.S. Application 07/242,482, now abandoned. Adang's involved U.S. Patent 5,380,831, which issued from Application 08/057,191, filed May 3, 1993, was accorded benefit for purposes of priority of the invention of Count 2 of the filing date of Adang's U.S. Application 07/242,482 (Paper No. 148, pp. 66-68).

To satisfy its initial burden, Fischhoff argues first that it actually reduced an embodiment of Count 2 not corresponding to Claims 41-43 of its involved application to practice no later

than December 29, 1987. That is the date when synthetic <u>Bt</u> genes designed and ordered by Drs. Perlak and Fischhoff no earlier than September 8, 1987, were first constructed in accordance with the method of Claim 3 of Fischhoff's involved application and Count 2 (FPB 125 (Paper No. 243)). Fischhoff argues that its inventors directed the synthetic <u>Bt</u> genes, "including a synthetic fully modified gene designed on September 8, 1987 and specifically noted to include plant-preferred codons)" (FPB 125), to be introduced "into plants, resulting in enhanced <u>Bt</u> protein expression that was observed at least as early as August 10, 1988 when the transformed plants had grown up" (FPB 125).

To decide whether Fischhoff has satisfied its initial burden to establish by clear and convincing evidence that it reduced an embodiment of Count 2 to practice prior to September 9, 1988, the earliest priority benefit date accorded Adang's involved patent, we need determine whether the evidence of record clearly and convincingly shows that at least one synthetic Bt gene designed by Fischhoff's inventors on or about September 8, 1987 (FPB 125), satisfies all the limitations of a modified Bt gene of a composition claim designated as corresponding to Count 2 or a Bt gene modified in accordance with all the limitations of a method claim designated as corresponding to Count 2, and the modified Bt gene worked for its intended purpose. See Mycogen Plant Sci.,

Inc. v. Monsanto Co., 243 F.3d 1316, 1332, 58 USPQ2d 1030, 1043
(Fed. Cir. 2001) (Paper No. 125):

"In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the interference count; and (2) he determined that the invention would work for its intended purpose." Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). In certain cases, determining that the invention works for its intended purpose will require testing. See Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996). "[W]hen testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur." Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 594-95, 44 USPQ2d 1610, 1615 (Fed. Cir. 1997).

To satisfy all the limitations of any claim designated as corresponding to Count 2, the claimed synthetic <u>Bt</u> gene or synthetic <u>Bt</u> gene made in accordance with a method claim designated as corresponding to Count 2, must (1) encode a <u>Bt</u> insecticidal protein, and (2) show enhanced expression in a plant transformed thereby relative to the native <u>Bt</u> gene from which the synthetic or modified <u>Bt</u> gene was derived. We conclude that all the synthetic <u>Bt</u> genes or methods for designing synthetic <u>Bt</u> genes or modifying native <u>Bt</u> genes of the claims designated as corresponding to Count 2 require that the synthetic <u>Bt</u> gene encode a <u>Bt</u> insecticidal protein. Moreover, we conclude that all the claimed synthetic <u>Bt</u> genes or methods for designing synthetic <u>Bt</u> genes or modifying native <u>Bt</u> genes designated as corresponding

to Count 2 require enhanced expression of the synthetic Bt gene encoding said Bt insecticidal protein in a plant transformed by said synthetic Bt gene. We interpret the phrases "modifying a . . . gene . . . to enhance the expression of said [insecticidal] protein in plants" (Claim 3 of Fischhoff's involved application), "designing a . . . gene to be more highly expressed in plants" (Claim 39 of Fischhoff' involved application), "synthetic gene . . . which is more highly expressed in plants" (Claim 40 of Fischhoff's involved application), "method of designing a synthetic . . . gene to be more highly expressed in plants" (Claims 1 and 11 of Adang's involved patent), "method of improving the expression of a dicot plant of a . . . deltaendotoxin protein" (Claim 1 of Barton's involved application), and "method of designing a synthetic . . . gene to be more highly expressed in plants" (Claims 20 and 21 of Barton's involved application), as functional limitations of the synthetic Bt genes encoding the insecticidal Bt protein defined by the claims in which the phrases appear. Our conclusion is consistent with the interpretation of functional language in claims of related and commonly owned Adang et al., U.S. Patent 5,567,600, issued October 22, 1996, Adang et al, U.S. Patent 5,567,862, issued October 22, 1996, and their parent, Adang's involved U.S. Patent 5,380,831, issued January 10, 1995, in Mycogen Plant Sci., Inc.

v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), and Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001). First, the Federal Circuit recognized that all three Mycogen patents had common language with related claim construction issues in Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1326-27, 58 USPQ2d at 1038:

[T]he claim construction issue here relates to both the '600 and the '862 patent, as well as the original '831 parent patent, as all three patents contain claims that use the language disputed herein.

See the underlined language common to Claim 1 of Adang's involved patent and Claim 1 of Adang's U.S. Patent 5,567,600 below:

1. (U.S. Patent 5,380,831) A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence.

- 1. (U.S. Patent 5,567,600) A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:
- (a) <u>analyzing the coding sequence of a gene derived</u> from a Bacillus thuringiensis which encodes a pesticidal protein toxin,
- (b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to modification, said

modification comprising reducing the number codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence;

- (c) inserting said modified sequence into the genome of a plant cell; and
- (d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said synthetic <u>Bacillus thuringiensis</u> gene is expressed to produce a pesticidal protein toxin.

Having compared the same two claims, the court said in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d at 1311, 58 USPO2d at 1895:

The two steps recited in claim 1 of the '831 patent are also found in claim 1 of the '600 patent. The two claims differ in that claim 1 of the '600 patent includes two further steps in addition to the two steps that are common to both claims, and it also includes additional limitations requiring removal of a number of codons having the nucleotide bases guanine and cytosine (GC) in codon positions II and III.

With respect to claim construction, the terms of the claims of the '831 patent must be construed consistently with the same terms in the '600 patent. Claim construction was litigated in Delaware I before both the district court and this court, and determination of that issue was necessary to the judgment in that case.

In Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), the patentability of the subject matter defined by Claim 1 of Adang et al., U.S. Patent 5,567,600, under 35 U.S.C. § 102(g)/103 was at issue. Considering the

evidence before it, evidence also of record in this interference, the court stated at 243 F.3d at 1335, 58 USPQ2d at 1045:

"The parties do not dispute, and the record shows, that Fischhoff and Perlak at Monsanto designed, built and tested synthetic Bt genes that contained the structure claimed in Mycogen's patents before Mycogen filed its patent applications on September 9, 1988." Mycogen [Plant Science, Inc. v. Monsanto Co.], 61 F.Supp.2d [199] at 239 [(D. Del. 1999)]. The evidence of record shows that Monsanto's synthetic Bt genes were inserted into plants, which were then grown and successfully tested for increased Bt expression in early- to mid-August 1988. Id. at 222.

With regard to the structural and procedural limitations of the claims defining Mycogen's invention, the Federal Circuit explained, 243 F.3d at 1335, 58 USPQ2d at 1046:

Mycogen does not dispute that the genes and resulting plants created and successfully tested by Monsanto's scientists prior to Mycogen's date of constructive reduction to practice met all of the limitations of the product claims of the '600 and '862 patents. Nor does Mycogen dispute that the methods employed by Monsanto's scientists to make these genes and plants met the limitations of the process claims of the '600 and '862 patents.

The Federal Circuit recognized the functional limitations on the synthetic genes in the claims defining Mycogen's invention.

Accordingly, it declined to grant Monsanto a date of actual reduction to practice prior to its successful testing for "increased <u>Bt</u> expression in early- to mid-August 1988" (243 F.3d at 1335, 58 USPQ2d at 1045), based on evidence <u>nunc pro tunc</u> (243 F.3d at 1335, 58 USPQ2d at 1046):

The precise language of the reduction to practice test states "[i]t is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation of the invention represented by the counts."

Breen v. Henshaw, 472 F.2d 1398, 1401, 176 USPQ 519, 521 (CCPA 1973) (emphasis added); see also Estee Lauder, 129 F.3d at 593, 44 USPQ2d at 1614 (summarizing past cases by stating "[t]hese cases trumpet, therefore, the principle that a reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose").

The purpose of the invention was to produce a pesticidal protein toxin in plants through the higher expression of the Bt gene. The record and the district court's opinion clearly show that Monsanto appreciated that the invention worked for this purpose. Monsanto tested the plants resulting from their modified genes specifically looking for the presence of increased Bt protein. See Mycogen, 61 F.Supp. 2d at 222. Moreover, scientists, upon learning of the test results indicating that their gene caused increased Bt expression, immediately appreciated the significance of the results. The analyst in charge of the testing testified that the results "proved that we [Monsanto] had succeeded, that the synthetic gene worked and worked exceptionally well in plants. Id. at 240 (alteration in original).

Suffice it to say that the Federal Circuit found "a legally sufficient evidentiary basis" for the Delaware District Court's conclusion that Monsanto (there, as here, Fischhoff and Perlak) reduced the invention claimed in Mycogen's U.S. Patent 5,567,600 to practice before September 9, 1988, specifically, "in early-to mid-August 1988." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1311, 58 USPQ2d at 1045.

The Federal Circuit explained the relevance of its statements on review of the Delaware District Court's findings of

fact and conclusions of law regarding the patentability of Claim 1 of Mycogen's Adang et al., U.S. Patent 5,567,600, to Claim 1 of Adang's involved U.S. Patent 5,380,831, designated as corresponding to Count 2 of this interference, in review of the Southern California District Court's findings of fact and conclusions of law relative to the patentability of Claim 1 of U.S. Patent 5,380,831 in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001). At 1311, 58 USPQ2d at 1895, the court said:

The two steps recited in claim 1 of the '831 patent are also found in claim 1 of the '600 patent. The two claims differ in that claim 1 of the '600 patent includes two further steps in addition to the two steps that are common to both claims, and it also includes additional limitations requiring removal of a number of codons having the nucleotide bases guanine and cytosine (GC) in codon positions II and III.

With respect to claim construction, the terms of the claims of the '831 patent must be construed consistently with the same terms in the '600 patent. Claim construction was litigated in Delaware I before both the district court and this court, and determination of that issue was necessary to the judgment in that case.

Similarly, a finding that Monsanto reduced the four-step invention of the '600 patent to practice before September 9, 1988 (the date on which it is undisputed that Mycogen reduced the invention to practice), necessarily means that Monsanto also reduced the two-step invention of the '831 patent to practice before September 9, 1988. As with claim construction, prior invention by Monsanto was argued before the district court and this court in <u>Delaware I</u> and was critical to the judgment.

Having considered the Federal Circuit's (1) conclusions on review of the decisions of the Delaware and Southern California district courts and supporting opinions, and (2) the evidence of record in each of the district court proceedings upon which conclusions of law were based, we necessarily find, as did the Federal Circuit in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d at 1311, 58 USPQ2d at 1895, that "Monsanto also reduced the two-step invention of the '831 patent to practice before September 9, 1988." See Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1335, 58 USPQ2d at 1045:

"The parties do not dispute, and the record shows, that Fischhoff and Perlak at Monsanto designed, built and tested synthetic Bt genes that contained the structure claimed in Mycogen's patents before Mycogen filed its patent applications on September 9, 1988." Mycogen[Plant Science, Inc. v. Monsanto Co.], 61 F.Supp.2d[199] at 239[(D. Del. 1999)]. The evidence of record shows that Monsanto's synthetic Bt genes were inserted into plants, which were then grown and successfully tested for increased Bt expression in early- to mid-August 1988. Id. at 222.

It is unnecessary to identify the precise date Fischhoff actually reduced an embodiment of Claim 1 of Adang's involved U.S. Patent 5,380,831 to practice "in early- to mid-August 1988." It is sufficient that the date is earlier than September 9, 1988. Nevertheless, all of Monsanto's testimonial evidence and laboratory notebooks point to August 10, 1988, as the specific date Junior Party Fischhoff recognized and appreciated that

plants grown from plant cells transformed by its modified <u>Bt</u> gene encoding insecticidal protein and tested for expression thereof showed insecticidal <u>Bt</u> protein production in amounts higher than produced by plants transformed by the native <u>Bt</u> gene.

See the arguments on pages 143 to 152 of Fischhoff's Priority Brief (FPB 143-152), the material facts Fischhoff relied upon, and the citations to the record in support of those material facts. We find, consistent with <u>Mycogen Plant Sci., Inc. v.</u>

<u>Monsanto Co.</u>, 243 F.3d at 1335, 58 USPQ2d at 1045, a legally sufficient evidentiary basis to conclude that Fischhoff actually reduced an invention of Claim 1 of Adang's U.S. Patent 5,380,831 corresponding to Count 2 of this interference to practice prior to September 9, 1988.

II. Fischhoff' Date Of Conception

In that Fischhoff has established that it actually reduced the invention of Count 2 to practice before the earliest filing date accorded the subject matter claimed in Senior Party Adang's involved U.S. Patent 5,380,831 for purposes of establishing priority of invention, i.e., the September 9, 1988, filing date of Adang's grandparent Application 07/242,484, Adang still may show that it was first to invent the subject matter of Count 2 by showing:

. . . either that he was first to reduce the invention to practice or that he was first to conceive the invention and

then exercised reasonable diligence in attempting to reduce the invention to practice from a date just prior to the other party's conception to the date of his reduction to practice. 35 U.S.C. § 102(g) ("In determining priority of invention . . . there shall be considered . . . the reasonable diligence of one who was the first to conceive and last to reduce to practice, from a time prior to conception by the other."); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996).

Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d at 1310, 58 USPQ2d at 1894. Because "Adang . . . states that Adang's actual reduction to practice of the invention defined by Count 2 was not prior to the filing date of the earliest application upon which Adang is entitled to rely for benefit (i.e., USSN 07/242,482, filed September 9, 1988)" (AB 43), to establish priority of invention with regard to Count 2, Adang must show that it was first to conceive of the invention of Count 2 and exercised reasonable diligence in attempting to reduce the invention to practice from a date prior to the date of Fischhoff's conception to the date of Adang's first reduction to practice on September 9, 1988. Thus, before we consider and evaluate the merits of Adang's showing, we must first establish the date Fischhoff first conceived of the invention of Count 2.

It is important to note that the parties to this interference must be concerned with the scope of subject matter encompassed by Count 2, not merely the subject matter defined by Claims 1 and 11 of Adang's involved U.S. Patent 5,380,831.

Accordingly, we are not bound in this interference by the conclusion of our reviewing court in Mycogen Plant Sci., Inc. v.

Monsanto Co., 252 F.3d at 1314, 58 USPQ2d at 1897, that the evidence before the District Court for the Southern District of California was insufficient to support a finding that Fischhoff conceived of the invention of Claim 1 or 11 of Adang's involved U.S. Patent 5,380,831 by October 1986, for purposes of summary judgment. While Count 2 of this interference is indeed alternatively directed to Claims 1-12 of Adang's involved U.S. Patent 5,380,831, it also is alternatively directed to Claims 3, 5, and 39-40 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, or any of Barton's pending claims.

Fischhoff argues (FPB 125):

The evidence now of record in this interference establishes that Fischhoff conceived of subject matter of Count 2 at least as early as October 30, 1986 when Dr. Fischhoff prepared a written memorandum setting out the inventors' plans for modifying the "native" (wild-type) Bt insecticidal protein structural gene sequences in order to enhance protein expression in plants.

We proceed to consider whether the evidence of record in this interference warrants our finding that Fischhoff conceived of the invention of Count 2 no later than October 30, 1986.

Fischhoff points to a written memorandum as the primary support for its testimonial evidence that it conceived of the invention of Count 2 of this interference no later than

October 30, 1986. First, we compare the memorandum's teaching as it relates to the invention of Count 2 as represented by Fischhoff's claims, not the invention of Count 2 as represented by Adang claims. Accordingly, we need not be overly concerned, as was the Federal Circuit in Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d at 1312-14, 58 USPQ2d at 1896-97, with Adang's claim limitations requiring "a greater number of codons preferred by the intended plant host" or "the frequency of codon usage of the plant" (e.g., Claims 1 and 11 of Adang's U.S. Patent 5,380,831). Rather, we need consider whether the "written memorandum" presents "'a definite and permanent idea of the complete and operative invention [of Claim 3 of Fischhoff's involved application], as it is therefore to be applied in practice.' Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) . . .", <u>Kridl_v. McCormick</u>, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997). Moreover, the invention of Claim 3 of Fischhoff's involved application must be so clearly defined in the "written memorandum" that "only ordinary skill would have been necessary to reduce the invention to practice, without extensive research or experimentation," Burroughs-Wellcome Co. v. Barr Labs., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994).

But an inventor need not know that his invention will work for conception to be complete. Applegate v. Scherer,

332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. $\underline{\text{Id.}}$

Claim 3 of Fischhoff's involved application is a "method for modifying a wild-type structural [\underline{Bt}] gene sequence which encodes an insecticidal protein of [\underline{Bt}] . . . to enhance the expression of said protein in plants" comprising the steps of (FPB 163) (emphasis added):

- (a) removing polyadenylation signals contained in said wild-type gene while retaining a sequence which encodes said protein; and
- (b) removing ATTTA sequences contained in said wild-type gene while retaining a sequence which encodes said protein.

To disclose all the limitations of method Claim 3 of Fischhoff's involved application, to which Count 2 of this interference is alternatively drawn, Fischhoff's written memorandum must disclose modifying a native Bt gene encoding insecticidal Bt protein "to enhance the expression" of insecticidal Bt protein in a plant by (a) removing polyadenylation signals from the native Bt gene while retaining a sequence which encodes insecticidal Bt protein, and (b) removing ATTTA sequences from the native Bt gene while retaining a sequence which encodes insecticidal Bt protein (FPB 163).

As primary support for Fischhoff's testimonial evidence that Fischhoff and Perlak conceived of the invention of Count 2, more

particularly Claim 3 of Fischhoff's involved application,
Fischhoff points to a written memorandum purportedly dated
October 30, 1986 (FPB 126):

In a memorandum dated October 30, 1986 (MDX 1478, 1190, 1199, and 1455), Dr. Fischhoff memorialized his discussions with Dr. Perlak, writing that the way to achieve enhanced expression of the Bt gene was to modify the coding sequence to remove polyadenylation sequences, ATTTA sequences, and other A-T rich sequences, while retaining its ability to encode the amino acid sequence of the Bt protein. That memo specifies all the material limitations of the Count 2 embodiment defined by Fischhoff claim 3 and describes in detail the methods subsequently practiced by Fischhoff to modify the Bt structural gene. While the memo does not contain a specific statement of use of plant-preferred codons in the course of the modification, Drs. Perlak and Fischhoff testified they had the use of such codons in mind when the memo was prepared and that modifications were actually accomplished by replacing codons of the native gene with plant-preferred codons by site directed mutagenesis using oligonucleotides or by synthesizing a gene from scratch, which is an embodiment of Count 2 defined by Adang claim 1. memorandum became the blueprint for modifying Bt genes of the Fischhoff invention.

Upon examination of the written memorandum itself (MDX 1478, 1190, 1199, and 1455), aside from any interpretive or colorful testimony, we find:

- (1) The documentary exhibits designated MDX 1478, 1190, 1199, and 1455 are substantially identical. Accordingly, we need cite and discuss only MDX 1478 hereafter.
- (2) MDX 1478 presents a three page document. The first page of MDX 1478 reads as follows:

RCCCV1::ECLAWS

JOB 123

ATRICH.DIS; 2557

File:

DSA100: [NETUSER.NP] ATRICH.DIS; 2557[2]

Owner UIC: Account:

OPSYS

Priority:

100

Submit queue:

AA320AS1

Submitted:

13-FEB-1997 13:18:29.24

Printer name: Executor queue:

AA320LW1 16/600 PS@CV AA3

VMS node:

AA320AS1 RCCCV1

Data Format:

TEXT

Form:

LTR_12

Digital Equipment Corporation VAXshare Print Server R1.2-EP02

VAX/VMS V5.5-2

- (3) Pages 2 and 3 of the document are two pages of printed text numbered MNP-001-001088 and MNP-001-001089. At the bottom right of each page appears the word "CONFIDENTIAL."
- (4) But for the date 13-FEB-1997 after "Submitted:", no page of the three-page document is dated.
- (5) We find in the document the following significant background information (footnotes inserted into text):
 - . . . The chimeric B.t.k. toxin genes utilized in these experiments have included both truncated (pMON9711 and pMon9713) and full-length (pMON9712) coding sequences

We surmise that "ATRICH" means A+T RICH, <u>i.e.</u>, mRNAs with a high A+T composition. We find interpretations consistent therewith in testimony of record.

In order to increase and optimize the expression of B.t.k. in plants it will be necessary to increase the level of stable B.t.k. mRNA. In the case of tomato such an increase would lead to higher levels of toxin production and greater insecticidal activity. In the case of tobacco no insecticidal activity can be expected until chimeric genes have been constructed which permit the production of stable mRNA. [(001088)]

. . . Instability of the B.t.k. mRNA could be due to its unusual base composition. Genes from Bacillus species typically have a base composition of greater than 60% A+T. . . . By comparison the NPTII coding sequence from E. coli whose RNA is expressed in plants at much higher levels than B.t.k. is 47% A+T. Typically, plant coding sequences are about 50% to 55% A+T. [(001088)]

It is possible that mRNAs which have a high A+T composition are inherently unstable in plant cells either due to their base composition per se or because they are unable to fold into proper stabilizing structures. It is also possible that the instability of these mRNAs is due to the presence of specific oligonucleotide sequences. Possible functions of such specific oligonucleotides which could lead to instability of the transcribed mRNA include:

- a. Specific signals for nucleolytic degradation of the RNA.
- b. Signals for improper polyadenylation of the RNA.
- c. Premature termination of transcription.
- d. Signals for improper splicing of the RNA.

Other functions for specific oligonucleotide sequences leading to instability are also possible. [(001088)]

Specific signals rich in A+T are known to function in at least two of the cases listed above. It has recently shown by Shaw and Kamen [(Shaw, G. et al., R., Cell, Vol. 46, pp. 659-667 (1986))] that a 51 nucleotide sequence composed solely of A and T can cause a normally stable mRNA to become very unstable. In addition they show that many animal cell mRNAs known to be unstable contain A+T rich sequences; these A+T rich sequences usually contain the specific short oligonucleotide ATTTA. It is also known that part of the signal for polyadenylation of mRNA is the presence of a specific short oligonucleotide in the mRNA.

These polyadenylation signals are typically A+T rich. In animal cell mRNAs the consensus signal is AATAAA; variants of this signal known to function in animal cells contain at least five A or T residues in the six nucleotide sequence [(Wickens, M. et al., Science, Vol. 226, pp. 1045-1051 (1984))]. In plant cells, several similar polyadenylation signals are known; these signals contain at least four A or T residues in the six nucleotide sequence [(Dean, C., et al., Nucleic Acids Research, Vol. 14, pp. 2229-2240 (1986))]. [(001088-001089)]

- (6) On the last page of MDX 1478 we find teaching material to the question of conception of Count 2. The important paragraph reads (MDX 1478, last page, first full para.) (emphasis added):
 - The B.t.k. coding sequence in pMON9711 contains many long stretches composed solely of A and T residues. This sequence also contains 15 copies of the sequence ATTTA and most of the potential polyadenylation signals which have been identified in either animal or plant cell mRNAs. Based on this analysis, we suggest that the instability of B.t.k. mRNA in plant cells is a function of its high A+T content; this might be due to overall A+T composition or the presence of specific A+T rich signals or both. We also predict that changing the base composition of the B.t.k. coding sequence to a lower A+T content and/or removal of specific oligonucleotide signals rich in A+T will lead to a significant increase in stable B.t.k. mRNA in plant cells.
- (7) Finally, on the last page of MDX 1478, we find described alternative methods and/or approaches for altering the base composition of the B.t.k. gene. One approach is site-directed mutagenesis "designed to change individual nucleotides or groups of nucleotides but would not alter the amino acid sequence of the protein produced" (MDX 1478, last page, third full paragraph).

Another approach "involves replacement of relatively large segments of the B.t.k. gene with chemically synthesized segments which code for the same amino acids but which utilized codons of lower A+T content" (MDX 1478, last page, last paragraph).

We do not hesitate to find that the Fischhoff's written memorandum (MDX 1478) shows that Fischhoff's inventors had a definite and permanent idea of the complete and operative invention of Claim 3 of Fischhoff's involved application corresponding to Count 2 of this interference at the time it was written. Kridl v. McCormick, 105 F.3d at 1449, 41 USPQ2d at 1689; Coleman v. Dines, 754 F.2d at 359, 224 USPQ at 862. The more interesting question is whether Fischhoff's written memorandum (MDX 1478) so clearly defines the idea "that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." Burroughs-Wellcome Co. v. Barr Labs., 40 F.3d at 1228, 32 USPQ2d To answer that question, we particularly note that an inventor may have a definite and permanent concept of an invention without knowing that the concept will work. Id. at 1228, 32 USPQ2d at 1919.

But an inventor need not know that his invention will work for conception to be complete. Applegate v. Scherer, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice. Id.

Thus, "[t]he question is not whether . . . [Fischhoff] reasonably believed that the invention would work for their intended purpose . . . but whether the inventors had formed the idea . . . in sufficient final form that only the exercise of ordinary skill remained to reduce it to practice." <u>Burroughs-Wellcome Co. v.</u>

Barr Labs., 40 F.3d at 1231, 32 USPQ2d at 1922.

Adang does not deny Fischhoff's argument that the evidence of record establishes that Drs. Fischhoff and Perlak worked diligently from October 30, 1986, the alleged date of the written memorandum in which they memorialized their conception of every feature of the invention of Claim 3 of Fischhoff's involved application corresponding to Count 2, until they actually reduced an embodiment thereof to practice no later than September 9, 1988, allegedly no later than August 10, 1988, the date when they first recognized and appreciated that the method of Claim 3 of Fischhoff's involved application worked as intended. the efforts of Drs. Fischhoff and Perlak, including the work performed by others at their direction and/or order, to reduce an embodiment of their invention to practice continued for a period of at most twenty-two months, the evidence does not indicate that the work required to reduce an embodiment of their invention to practice exceeded the ordinary skill of the artisan. The written memorandum provides enough specific guidance and direction that

the work remaining for Fischhoff and Perlak to reduce an embodiment thereof to practice, while extensive, was routine. The subsequent research and experimentation performed had as its purpose the optimization of a definite and complete solution to a The work was not designed to solve an unsolved problem. The written memorandum did not merely pose a problem. written memorandum presented a solution to that problem. written memorandum explicitly states, "We also predict that changing the base composition of the B.t.k. coding sequence to a lower A+T content and/or the removal of specific oligonucleotide signals rich in A+T will lead to a significant increase in stable B.t.k. mRNA in plant cells" (MDX 1478). We find no evidence of record inconsistent with our present finding that Fischhoff's written memorandum conceived of the invention of Claim 3 of Fischhoff's involved application corresponding to Count 2 as of its date.

However, the testimony of Fischhoff's inventors, and the corroborating testimony of associates acting at their design and direction, that Fischhoff's inventors conceived of the invention of Count 2 no later than October 30, 1986, may not be sufficient to establish October 30, 1986, as the date they first conceived of the invention of Count 2. An inventor's testimony, standing alone, is generally insufficient to prove conception without

documentary evidence of its communication to others. Price v.
Symsek, 988 F.2d 1187, 1194, 26 USPQ2d 1031, 1036 (Fed. Cir.
1993). Because conception is a mental act, courts generally require corroborating evidence showing a contemporaneous disclosure to others. Burroughs-Wellcome Co. v. Barr Labs.,
40 F.3d at 1228, 32 USPQ2d at 1919. Here, Fischhoff presents us with, what appears on its face to be, an undated written memorandum (MDX 1478).

We deem it necessary that Fischhoff's written memorandum not only establish (1) conception of the invention of Count 2 by Fischhoff prior to September 9, 1988, but also establish (2) the date on which Fischhoff conceived of the invention disclosed therein. Fischhoff argues that its written memorandum is dated October 30, 1986 (FPB 126). To show that its written memorandum is dated October 30, 1986, Fischhoff argued (FPB 65):

October 30, 1986 is the date on which I really memorialized all of our thoughts on paper and set about drafting the final version of a memo, what we would now call a conception document, that outlined the problem, the issues in the Bt genes, what we had seen before, what the symptoms were, then our ideas for the solution, namely resynthesizing, come up with a synthetic Bt gene that would fix all those problems. . . . October 30 is really when we decided that we had enough ideas and knew the solution to the problem to really set it down on a piece of paper that we would be committed to as our approach to the solution. And that was important to us to actually write it and document it and then paste it into our laboratory notebooks.

(MR 0446, Delaware I trial transcript, p. 1087, l. 14-22, and

p. 1088, l. 16-24). Fischhoff testified (FPB 66-67):

. . . By the end of October 1986, we had this firm idea in mind and actually wrote it down.

(MR 0467, Delaware II trial transcript, p. 1931, l. 7-22). The basis for the October 30, 1986, date is the following testimony and supporting evidence (FPB 67):

Dr. Fischhoff testified that MDX 1427 (See also MDX 1197, 1460) and MDX 1478 (See also 1190, 1199, 1455) are the directory listing from the VACS [sic] computer system that indicates that a document called "ATRICH.DIS" was created by Dr. Fischhoff on October 30th, 1986, and the document itself as printed out from the Monsanto computer system.

(MR 0467-0468, Delaware II trial transcript, p. 1931, l. 24, to

p. 1932, l. 11). Ultimately, Dr. Fischhoff testified (FPB 68):

I discussed it [the October 30^{th} memo, MDX 1478] (See also 1190, 1199, 1455) with others, but I was the one who actually drafted it and put the words to paper. It was pretty widely distributed.

(MR 0446, Delaware I trial transcript, p. 1090, 1. 2-12).

We find sufficient testimony by Monsanto's employees to corroborate the fact that the content of the written memorandum, if not the written memorandum itself, was distributed in-house or otherwise communicated to persons working for Monsanto who would have been interested in its subject matter. For example, Dr. Stephen Rogers, Dr. Fischhoff's group leader, testified (FPB 88):

[I]n our meeting [around September or October of 1986] . . . I asked him[, Dr. David Fischhoff,] to put together a -- kind of a summary plan, the thinking that had gone into where we were going and what kind of things we might be doing. And so David prepared this memo that did

describe that. [MDX 1464 (see also 1441, 1484)] actually is the memo pasted into his book, but at some time or another -- I don't remember exactly when -- he had given me a copy of this.

(MR 1036-1037, Delaware I trial transcript, p. 1033, l. 22, to p. 1036, l. 3). Dr. Rogers also testified that (FPB 90-91):

David Fischhoff pasted [the same document, MDX 1464 (see also MDX 1441, 1484),] in his notebook. . . . The date on this document is December 12th, 1986. . . . I saw it sometime prior to that as a memo, before it got pasted in the notebook. So sometime between our discussion and when it went into the notebook here.

(MR 1038, Delaware I trial transcript, p. 1042, 1. 7-17).

An associate of Dr. Perlak, Dr. Harry Klee testified that he knew of the existence Dr. Fischhoff's "list of ideas regarding synthesizing or modifying a Bt gene" (MR 0654, Delaware I trial transcript, p. 997, 1. 2-7). When asked if he recalled seeing the type of work Dr. Perlak was doing with <u>Bt</u> genes encoding toxin in late 1986/early 1987, Dr. Klee testified:

A. Yes. I think there were three basic things that were guiding what he was trying to do with that gene. Number one, he was trying to remove sequences which were thought to destabilize plant gene expression. These were so-called ATTTA sequences. That was sort of the first rule.

The second rule was he was looking to take out what were referred to as polyadenylation signals which were sequenced that would cause the gene to stop being made in the plant.

And then the third part was, he was trying to restructure the gene so that it encoded the same protein, but used what were referred to as plant-preferred codons,

as opposed to the bacterial. And all three of those were elements of the redesign of the gene.

(MR 0655-0656, Delaware II trial transcript, p. 1871, 1. 12, to p. 1872, 1. 3). Dr. Klee testified that the rules the <u>Bt</u> project was going to follow in redesigning the <u>Bt</u> gene were "common knowledge in the group. It was, again, discussed almost weekly at group meetings. And it was a major undertaking. It was something that was discussed with great regularity" (MR 0656, Delaware II trial transcript, p. 1872, 1. 4-10). When asked the time frame in which he became aware of the rules, Dr. Klee testified that "[Dr. Roger's Progress on Person Goals-1986, dated December 19, 1986 (MDX 1470)] . . . helps . . . to date it to the fall of 1986" (MR 0656, p. 1872, 1. 11-17).

Most significant to our finding the date Fischhoff first conceived of the subject matter of Count 2, David Fischhoff signed and applied the date December 12, 1986, to each page of the previously undated two page written memorandum which is said to establish Fischhoff's conception of the invention of Claim 3 of Fischhoff's involved application corresponding to Count 2 on October 30, 1986 (MDX 1478), pasted each page onto Fischhoff's Monsanto Company laboratory notebook (MDX 1463) pages No. 3547889 entitled "Expression of A+T rich Genes in Plants" and No. 3547890 entitled A+T rich (p.2), and again signed each laboratory notebook page to which a page of the written memorandum dated

December 12, 1986, had been pasted, and again dated each page December 12, 1986 (MDX 1464). Both of Monsanto Company laboratory notebook pages No. 3547889 and No. 3547890 are signed and dated as read and understood by Dannette C. Ward on December 15, 1986 (MDX 1464). Monsanto Company laboratory notebook pages No. 3547889 and No. 3547890 are significant because they present Fischhoff's written memorandum, the only documentary evidence submitted by Fischhoff which describes the invention defined by Count 2, in a form actually signed and specifically dated by an inventor, and actually signed and specifically dated as read and understood by another (MDX 1464). Moreover, the pasting of Fischhoff's written memorandum into Fischhoff Monsanto Company laboratory notebook is corroborated by testimony of at least one noninventor, Dr. Rogers (MR 1038, Delaware I trial transcript, p. 1042, l. 7-17). Accordingly, we find that Fischhoff has clearly and convincingly established that it conceived of the invention of Count 2 of this interference no later than December 12, 1986.

While Fischhoff argues that the date when the written memorandum was drafted was October 30, 1986, the evidence does not clearly and convincingly support that date. Aside from the testimonial evidence of others which does not identify the exact date the written memorandum was drafted no earlier than the fall

of 1986 and no later than December 12, 1986, Fischhoff points to a printout from a VAX computer system (MDX 1427) as evidence that the written memorandum was drafted on October 30, 1986 (FPB 67, Fact 157).

- Q. And when did you come up with the firm idea about what you would do to solve the problem of the Bt expression?
- A. By the end of October 1986, we had we had this firm idea in mind and actually wrote it down.
- Q. Okay. Let me show you what is exhibits Plaintiff's Exhibits 26 and 165 (handing exhibits to the witness). What does that document show, Dr. Fischhoff?
- A. Again, first, there's the -directory listing from the VACS [sic: VAX] computer system that indicates that a document called AT-rich dot dis was created by me on October $30^{\rm th}$, 1986. And the other part of this is the document itself as printed out from our computer system.

Page MNP-001-067481 of the printout (MDX 1427; also identified as Plaintiff Monsanto's Trial Exh. CA 96-133 RRM 165) reads in pertinent part:

\$ dir/date=all [eclaws.dafisc.jan87.text]

Directory RCC_USR2:[ECLAWS.DAFISC.JAN87.TEXT]

ATRICH.DIS;7 30-OCT-1986 15:42:15.72 7-FEB-1997 12:24:27.56 13-MAY-1997 22:25:31.15 10-FEB-1997 01:36:18.11

We find on page MNP-001-067481 of MDX 1427 no reference to ATRICH.DIS, <u>per se</u>. Rather the documentary exhibit refers to "ATRICH.DIS;7" (MDX 1427). Moreover, we find no explanation, and Fischhoff does not point to an explanation, of the significance

of the ";7" in "ATRICH.DIS;7" in this record. An explanation thereof is important because Fischhoff's undated written memorandum (MDX 1478) is identified in the VAX computer system as "ATRICH.DIS;2557" (MDX 1478). We find no explanation, and Fischhoff does not point to an explanation, of the significance of the ";2557" in "ATRICH.DIS;2557" in this record. Without further explanation, we are unable to relate "ATRICH.DIS;7" to "ATRICH.DIS;2557" for any purpose whatsoever. We find no basis upon which to accept the October 30, 1986 date of "ATRICH.DIS;7" as the date the written memorandum identified in MDX 1478 as "ATRICH.DIS;2557" was drafted. However, we find on this record substantial evidence that Fischhoff conceived of the invention of Claim 3 of Fischhoff's involved application corresponding to Count 2 no later than December 12, 1986 (MDX 1464).

Our finding that Fischhoff first conceived of the invention of Count 2 no later than December 12, 1986, does not prejudice either party's case for priority of the invention of Count 2 for two basic reasons. First, we find that the entries into Fischhoff's Monsanto Company laboratory notebook most assuredly provide the best evidence of the invention conceived by Fischhoff's inventors and the directions for future work to facilitate expression of Bt genes encoding toxic proteins in plants. When asked if it was his "practice to keep pretty

comprehensive records . . . of what you do on a day-in/day-out basis" (MR 0466, Delaware I trial transcript, p. 1089, 1. 9-10), Fischhoff answered (emphasis added):

- A. Yes. Certainly for our laboratory work we do.
- Q. Why do you do that?
- A. Well, it's important for scientists to document their work. We do a lot of experiments, not all of which work, and you have to know where you've been, what the results have been to figure out where you're going to move next and the laboratory notebook is the place to do it.

(Id.).

Second, as its case-in-chief for priority of invention,

Adang "alleges . . . that the invention as defined by Count 2 was

first conceived by M. Adang and E. Murray on November 6, 1985[,]

. . " and "alleges to have exercised reasonable diligence during

the critical period" (AB 43, para. la) just prior to October 30,

1986, to its constructive reduction to practice on September 9,

1988 (AB 44, first full para.). Accordingly, Adang's allegation

that it conceived of the invention of Count 2 before Fischhoff's

earliest conception date and evidence in support thereof is no

less persuasive and Adang's burden to show that it exercised

reasonable diligence during the critical period is reduced by

our finding that Fischhoff first conceived of the invention of

Count 2 no later than December 12, 1986.

B. Senior Party Adang's Case-In-Chief For Priority

I. Adang's Reduction to Practice

Adang acknowledges that it did not actually reduce an invention of Count 2 to practice prior to the September 9, 1988, filing date of the earliest application upon which Adang is entitled to rely for benefit (AB 43). Accordingly, to make its case for priority of the invention of Count 2 of this interference, Adang must show that it conceived of the invention of Count 2 prior to December 12, 1986, the date the evidence shows that Fischhoff first conceived of the invention of Count 2, and that it exercised reasonable diligence toward constructive reduction to practice of the invention of Count 2 throughout the critical period beginning just before Fischhoff's December 12, 1986, date of conception, until Adang's constructive reduction to practice on September 9, 1988. First quoting Christie v. <u>Seybold</u>, 55 F. 69, 76 (6th Cir. 1883) (Taft, J.), and then quoting Price v. Symsek, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993), the Federal Circuit instructed in Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1577, 38 USPQ2d 1288, 1290 (Fed. Cir. 1996):

[T]he person "who first conceives, and, in a mental sense, first invents . . . may date his patentable invention back to the time of its conception, if he connects the conception with the reduction to practice by reasonable diligence on his part, so that they are substantially one continuous act." . . . Stated otherwise, priority of invention "goes

to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice."

The party trying to show reasonable diligence "must account for the entire period . . . until his reduction to practice[, actual or constructive]." Griffith v. Kanamaru, 816 F.2d 624, 626, 2 USPQ2d 1361, 1362 (Fed. Cir. 1987). If periods of inactivity occur, each period of inactivity may be explained and excused for "reasonable everyday problems and limitations encountered by an inventor". Id. at 627, 2 USPQ2d at 1362. The question of diligence is essentially one of fact. In re Jolley, 308 F.3d 1317, 1329, 64 USPQ2d 1901, 1910 (Fed. Cir. 2002).

II. Adang's Case For Prior Conception Of Count 2 And Reasonable Diligence Toward Reduction To Practice

The count determines what evidence is relevant to the issue of priority. Case v. CPC Int'l, Inc., 730 F.2d 745, 749, 221

USPQ 196, 199 (Fed. Cir.), cert denied, 469 U.S. 872 (1984).

Here, Count 2 is alternatively directed to the invention defined by any one of Claims 1-4, 7, and 15-22 of Barton's U.S.

Application 07/827,906, filed January 30, 1992; any one of Claims 3, 5, and 39-40 of Fischhoff's U.S. Application

08/434,105, filed May 3, 1995; or any one of Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995.

Accordingly, to establish priority of the invention of Count 2 of

this interference, Adang must show that it was first to conceive the invention defined by any one of Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992; any one of Claims 3, 5, and 39-40 of Fischhoff's U.S. Application 08/434,105, filed May 3, 1995; or any one of Claims 1-12 of Adang's U.S. Patent 5,380,831, issued January 10, 1995, and that it exercised reasonable diligence toward later reducing that invention to practice. Eaton v. Evans, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000). Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 38 USPQ2d 1288 (Fed. Cir. 1996), adds at 1578, 38 USPQ2d at 1291:

Where a party is first to conceive but second to reduce to practice, that party must demonstrate reasonable diligence toward reduction to practice from a date just prior to the other party's conception to its reduction to practice. Griffith v. Kanamaru, 816 F.2d 624, 625-26, 2 USPQ2d 1361, 1362 (Fed. Cir. 1987).

Thus, our initial task is to determine if Adang was first to conceive of the invention of a claim corresponding to Count 2.

To establish prior conception of the invention of Count 2, Adang must show that prior to December 12, 1986, it had "a definite and permanent idea of the complete and operative invention,"

Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d at 1228,

32 USPQ2d at 1919; i.e., Adang must show it had possession of an invention having every feature recited in a claim to which Count 2 of this interference is alternatively directed and knowledge of

every limitation of that claim. <u>Coleman v. Dines</u>, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985). Moreover, "[c]onception must be proved by corroborating evidence which shows that the inventor disclosed to others his 'complete thought expressed in such clear terms as to enable those skilled in the art' to make the invention." <u>Id.</u> at 359, 224 USPQ at 862 (quoting <u>Field v. Knowles</u>, 183 F.2d 593, 601, 86 USPQ 373, 379 (CCPA 1950)).

<u>Price v. Symsek</u>, 988 F.2d 1187, 26 USPQ2d 1031 (Fed. Cir. 1993), explained the requirement at 1194, 26 USPQ2d at 1036-37 (quoting <u>Mergenthaler v. Scudder</u>, 11 App. D.C. 264, 278-79 (D.C. Cir. 1897)):

[C]onception by an inventor, for the purpose of establishing priority, can not be proved by his mere allegation nor by his unsupported testimony where there has been no disclosure to others or embodiment of the invention in some clearly perceptible form, such as drawings or model, with sufficient proof of identity in point of time. For otherwise[,] such facile means of establishing priority of invention would, in many cases, offer great temptation to perjury, and would have the effect of virtually precluding the adverse party from the possibility of rebutting such evidence.

However, the "rule of reason" applies. <u>Price v. Symsek</u>, 988 F.2d at 1195, 26 USPQ2d at 1037. <u>Price v. Symsek</u>, 988 F.2d at 1196, 26 USPQ2d at 1038, instructs:

[All of the evidence put forth . . . must be considered as a whole, not individually, in determining . . . [conception]. In other words, an inventor can conceivably prove prior conception by clear and convincing evidence although no one piece of evidence in and of itself establishes prior conception. It is sufficient if the

picture painted by all the evidence taken collectively gives the board "an abiding conviction" that [the inventor's] assertion of prior conception is "highly probable."

Now, let us examine Adang's evidence of prior conception of the invention of Count 2. Our examination takes two paths.

Adang first argues, and points to evidence purporting to show, that it conceived of the invention of Claim 1 of Adang's involved patent corresponding to Count 2 prior to October 30, 1986

(AB 44-47). Adang next argues, and points to evidence purporting to show, that it conceived of the invention of Claim 3 of Fischhoff's involved application prior to October 30, 1986

(AB 48-51).

a. Adang's purported conception of Claim 1 or 11 of Adang's U.S. 5,380,831 and reasonable diligence toward reduction to practice

(i) The count

Claim 1 or 11 of Adang's involved patent represents one definition of the invention of Count 2. Claim 1 of Adang's involved patent reads:

- 1. A method of designing a synthetic <u>Bacillus</u> thuringiensis gene to be more highly expressed in plants, comprising the steps of:
 - [a] analyzing the coding sequence of a gene derived from a <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and
 - [b] modifying a portion of said coding sequence to yield a modified sequence which contains a greater

number of codons preferred by the intended plant host than did said coding sequence.

In Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330, 58 USPQ2d 1030, 1041 (Fed. Cir. 2001), the Federal Circuit concluded that the Delaware district court's claim construction regarding the limitation "greater number of codons preferred" was correct. Accordingly, the modification step must "result in a higher number of those codons whose frequency in the native Bt gene was lower than their frequency in the plant host." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1330, 58 USPQ2d at 1041 (emphasis original). However, Claim 11 of Adang's involved patent is not so limited. Claim 11 reads:

- 11. A method of designing a synthetic <u>Bacillus</u> thuringiensis gene to be more highly expressed in plants, comprising the steps of:
 - [a] analyzing the coding sequence of a gene derived from a <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and
 - [b] modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant in which it is to be expressed.

While the Federal Circuit appeared to accept the Delaware district court's interpretation that a "'preferred codon' . . . [is] any codon that brings the modified Bt gene's codon frequency closer to that of the intended plant host," Mycogen Plant Sci.,

Inc. v. Monsanto Co., 243 F.3d at 1328, 58 USPQ2d at 1039, the

court recognized that there is a distinction between the limitations in the modification steps of Claims 1 and 11 of Adang's involved patent. At final hearing, Adang focused on the subject matter defined by Claim 1 of it involved patent.

Nevertheless, it is important to understand the relationship between the "number of codons preferred" and "frequency of codon usage" in Claims 1 and 11 of Adang's involved patent to finally determine whether Adang's focus and the evidence upon which it relies shows prior conception of the invention of Count 2, which Claims 1 and 11 alternatively define. Significantly, Adang's involved patent specification teaches that codon preferences in Bt relative to plants are critical to conception of the invention of Count 2 of this interference, whether represented by Claim 1 or Claim 11 of Adang's involved patent. Adang's U.S. Patent 5,380,831 teaches at column 7, lines 3-19:

To determine the frequency of usage of a particular codon in a gene, the number of occurrences of that codon in the gene is divided by the total number of occurrences of all codons specifying the same amino acid in the gene. Table 1, for example, gives the frequency of codon usage for Bt genes, which was obtained by analysis of four Bt genes whose sequences are publicly available. Similarly, the frequency of preferred codon usage exhibited by a host cell can be calculated by averaging frequency of preferred codon usage in a large number of genes expressed by the host cell. It is preferable that this analysis be limited to genes that are highly expressed by the host cell. Table 1 . . . for example, gives the frequency of codon usage by highly expressed genes exhibited by dicotyledonous plants, and monocotyledonous plants.

Adang argues (AB 45):

By 1985, . . . Drs. Adang and Murray recognized that . . . [tobacco plants transformed to express insecticidal amounts of <u>Bt</u> toxin protein] exhibited very low levels of <u>Bt</u> RNA. Dr. Adang and Dr. Murray discussed this <u>Bt</u> expression problem and proposed modifying the <u>Bt</u> DNA sequence in order to increase expression of <u>Bt</u> toxin genes in plants. On or about November 6, 1985, Dr. Adang and Dr. Murray memorialized their conception of a method for designing a synthetic insecticidal <u>Bt</u> gene by modifying a portion of the gene to have a greater number of plant preferred codons (See, <u>e.g.</u>, Facts 29, 33-39).

Dr. Adang and Dr. Murray provided credible testimony establishing a clear and permanent idea of the subject matter defined by Adang claim 1.

(ii) The evidence

We move directly to "[t]he draft abstract (AX-106E) dated November 6, 1985, that Adang initially planned to disclose at a scientific meeting [which] . . . reflects Dr. Adang's and Dr. Murray's concept to modify Bt genes to address premature termination of transcription during the expression of Bt genes" (AB 47, third full para.). The draft abstract (AX 106E) is, in its entirety, reproduced below (emphasis added):

ucla2



Abstract for UCLA symposium

NOVEL APPLICATION OF A BACILLUS THURINGIENSIS CRYSTAL PROTEIN FOR INSECT CONTROL

A continuing challenge in controlling pest insects is the development of insect resistant plants. One approach to accomplishing this objective is to express proteins in plants that are toxic to insects. Insect pathogens such as Bacillus thuringiensis provide a source for toxin genes. We recently described the cloning and characterization of full-length and toxic fragments of the Bacillus thuringiensis HD-73 crystal protein gene (Adang et. al.)

-More-(38%)

REDACTED

CONFIDENTIAL MC088384

EXHIBIT 36

2193

been engineered behind the matter (Orf 24) promoter of pTi15955. These promoter . . [illegible] cassettes were cloned into a binary micro T-DNA vector containing a plant selectable marker and using Agrobacterium tumefaciens transferred into tobacco plants. We have observed significant levels of truncated Bt peptides in callus and immature shoot tissue. However, expanded tobacco leaves

contain the expected <u>Bt</u> DNA but no immunoreactive peptides.

Preliminary analysis of RNA indicates processing at internal sites in the toxin gene. <u>It appears that for efficient</u>

<u>expression of this toxin in tobacco plants the coding</u>

<u>sequence must be modified to eliminate premature termination</u>

<u>of transcription</u>. Work is in progress to evaluate

-More-(93%)

REDACTED

CONFIDENTIAL MC088385

EXHIBIT 36

2194[.]

As the final page of Adang Exhibit No. 106E (AX-106E), the documentary exhibit provides what appears to be the following computer printout, the last seven (7) lines thereof:

-rw-rr- 1	188	1177	Sep	10	1986	syn.trunc.pro
-rw-rr- 1	188	602	May	13	1985	talk
-rw-rr- 1	188	776	Jan	29	1986	tom
-rw-rr- 1	188	1475	Nov	6	1985	ucla2
-rw-rr- 1	188	925	Aug	3	1986	vaughn.8.86
-rw-rr- 1	188	979	Dec	10	1985	west.blot
agrimad> gaertner /mnt/archives/ul.87/adang/papers ->						

CONFIDENTIAL MC088386

Exhibit 36

2195[.]

While we tend to agree with Adang's argument that "[t]his draft abstract (AX-106E) reflects Dr. Adang's and Dr. Murray's

concept to modify Bt genes to address premature termination of transcription during the expression of Bt genes" (AB 47, third full para.), that "concept" is merely an invitation to follow a certain path of experimentation. It is not a definite and permanent solution to the problem. We find no evidence in Adang's draft abstract (AX-106E) which shows that Adang conceived of an invention having all the features of Claim 1 of Adang's involved patent, or having all the features of any other claimed invention to which Count 2 of this interference is directed. Moreover, we have considered the merits of the disclosure in Adang's draft abstract (AX-106E) without questioning Adang's presumption that the designation "Nov 6 1985 ucla2" in the computer listing on page 2195 of AX-106E necessarily corresponds to the date the draft abstract (AX-106E) was drafted, even though the abstract does refer to "ucla2" in its first two lines (AX 106E, p. 2193). Nevertheless, Adang argues that, when the disclosure of the November 6, 1995, draft abstract is considered together with the inventors' testimony, the corroborating testimony of Ms. Stock, Dr. Romero-Severson and Dr. Sekar, and the cited publications showing the state of, and knowledge in, the art on November 6, 1985, the evidence as a whole establishes that Adang was first to conceive of the invention of Claim 1 of Adang's involved patent and thus Count 2 of this interference,

<u>i.e.</u>, prior to Fischhoff's December 12, 1986, conception of the invention of Count 2 (AB 47).

Adang argues that Drs. Adang and Murray exchanged ideas in October and November 1985 as to why Bt mRNA levels were low in plants transformed with native Bt gene sequences and "concluded that Bt DNA needed to be modified to increase expression and levels of Bt mRNA" (AB 46, para. 1). While Adang cites Facts 35-39 and 43 of its brief in support for these arguments, we need not question, and Fischhoff does not question, the truth of this statement. Again, whether or not Adang and Murray generally recognized that "Bt DNA needed to be modified to increase expression and levels of Bt mRNA [in plants]" (AB 46, para. 1), Facts 35-39 and 43 do not appear to describe a solution encompassed by Count 2. Fact 35 (AB 10) refers to an entry on page 13 of what appears to be a laboratory notebook page entitled "Bt Northerns," signed by Elizabeth Murray on 10-22-85, and signed as witnessed and understood by Michael J. Mownery (sic?) on 10/22/85 (AX 101B). The most pertinent portion of Dr. Murray's lab notebook quoted in Adang's Fact 35 reads (AX 101B) (emphasis added):

I wrote up the data from the other blots and measured the bands. The large OCS band was 1.2 Kb, the NPTII band was 1.25 and the Bt band was 1.7. The predicted sizes of 1.2 and . . . 1.8 for OCS and NPTII respectively were in good agreement. Bt may have some kind of premature termination signal. We spoke about S1 mapping the RNA

to show where the transcription was terminating. Then we could use the sequence information to site specifically mutagenize the premature termination region of the <u>Bt</u> gene.

Fact 35 also cites the record at AR 6040 (1427:18-1428:17) in further support of the quotation above taken from Dr. Murray's lab notebook (AB 10). AR 6040 is a record of Dr Adang's testimony in Delaware I (AR 6019; AR 6039, p. 1424, l. 18-19). With reference to the entries on Dr. Murray's lab notebook, p. 13 (AX 101B), Dr. Adang testified (AR6039-6041, pp. 1424, l. 18, to 1430, l. 2) (emphasis added):

- Q. Dr. Adang, going back to 1985, could you describe what work you were doing at Agrigenetics at that time?
- A. In the summer of 1985, we were working on the expression of native Bt genes in tobacco plants. We had we had put insects on these plants and we had observed that -we saw some kill the worms on these plants, but these Bt tobacco plants weren't killing the worms at a commercially-useful level.

We also saw a mono Bt protein in these tobacco plants was very, very low. So in the summer of '85 and continuing on, we started thinking about and working on trying to figure out what was happening in these plants, why the Bt gene wasn't working better. And we knew that we needed a solution to coming [sic] up with, you know, solving this problem of low Bt expression.

- Q. And did you arrive at a solution at that time?
- A. Yes, we did. In late 1985, Dr. Liz Murray and I came up with the solution of modifying Bt genes to make them more plant-like. And as part of these modifications, we would also remove a poly remove poly-A sites.
- .Q. Who was Dr. Murray?

- A. Dr. Murray, Liz Murray, was a post-doc who reported to me.
- Q. And how did you and Dr. Murray come up with the idea of removing poly-A signals?
- A. Well, I had been analyzing as I said, I was looking at the looking at these Bt tobacco plants and looking at the kill on these plants and seeing that they weren't killing like we wanted. And one of the experiments that Dr. Murray and I did together was a Northern blot experiment to look at look at the Bt RNA, because the Bt protein comes from RNA and we wanted to study the RNA.

A. The experiment that Dr. Murray did, that I want to talk a little bit about here, was a Northern blot experiment to look at the Bt RNA in these plants. And what we found regarding Bt RNA was that the Bt RNA was - first of all, there wasn't very much of it. It was in low amounts. Okay? And then this RNA was also a type of RNA we call poly-A RNA. So it had little A's on the tail. The RNA was poly-A.

But also importantly, that the RNA was chopped up so it was truncated. And the truncated size of the RNA was really - it was too short to make a toxic Bt protein. So we knew we had this problem.

And then at that time, because we knew - because we knew that it was poly-A RNA, then we began to think and study Bt genes for poly-A sites. And we knew that we - we knew that we needed to remove these poly-A sites that were stopping transcription so that we could solve this problem.

- Q. Now, is the work that you and Dr. Murray did with the Northern blot, is that reflected anywhere?
- A. Yes. That work is described in Liz Murray's notebook.
- Q. And would you look at Exhibit 492-A? And if we we had it retyped since the copy is so poor.

Is this what you are referring to?

- A. Yes, it is.
- Q. And what does this <u>page</u> in Dr. Murray's notebook show?
- A. Well, this page in Dr. Murray's notebook -

The words are written on the page and they're kind of retyped up here. And the line I want to point you to, it says that the Bt band was 1.7 KB [sic, Kb]. That meant that the Bt, the RNA was shorter than we needed to, so it was chopped up.

And Liz went on to state, Bt may have some kind of premature termination signal. And to continue, we spoke about S-1 mapping the RNA to show where the transcription was terminated. Then it says, then we could use the sequenced information to cite specifically mutagenize the premature termination region of the Bt gene.

What this means is that we saw this chopped-up RNA and we knew there was a premature termination signal Bt gene. And this termination signal was causing this chopped-up RNA.

And then this - the mention of site-specifically mutagenize the premature termination region of the Bt gene is that we wanted to go in. We wanted to modify the coding region of the Bt gene. And because the RNA had a poly-A tail, we knew that these were poly-A sites in the middle of the Bt gene that we needed to modify to enhance this expression.

- Q. And what is the date of this notebook page?
- A. October 22nd, 1985.
- Q. What were you doing in that time frame, late 1985, towards removing poly-A signals?
- A. In in late 1985, regarding these poly-A signals, we had I, personally, was doing a number of computer searches to identify the number of poly-A sites in Bt genes and to find out where they're located so that I might modify those sites and eliminate them.

- Q. And did you write down your concept of finding the poly-A sites and modifying the coding sequence to remove them?
- A. Yes, we did. We wrote this down. Liz Murray wrote it down in the notebook page and that's the page I just referred to. But I also wrote it down in a draft of an abstract that [sic, I] was preparing for a the UCLA symposium talk.
- Q. If you will look at Exhibit 125...
- A. Okay.
- Q. And is this the abstract you're referring to?
- A. Yes, it is.
- Q. And what is the date of this draft?
- A. If we turn to the third page, the date of this abstract is November 6^{th} , 1985.
- Q. And could you point specifically to where in this abstract you were referring to?
- A. I was referring to, on the second page of the abstract, where it says, preliminary analysis of RNA indicates processing at internal sites in the toxin gene. It appears that for efficient expression of this toxin in tobacco plants, the coding sequence must be modified to eliminate premature termination of transcription.

So I'm referring back to this - that we saw this chopped-up RNA and we knew it was polyadenylated. And that we knew we needed to solve this problem and modify the gene to eliminate these sites.

We are somewhat confused by Dr. Adang's testimony. He testified in Delaware I that Dr. Murray and he knew that the chopped-up RNA fragments Dr. Murray reported at her laboratory notebook page entitled "Bt Northerns," dated October 22, 1985

(AX 101B), had a poly-A tail (AR 6040, p. 1426, l. 9-14), and that because the RNA had a poly-A tail, they knew that there were poly-A sites in the middle of the Bt gene that had to be eliminated by removal or modification to enhance expression of the Bt toxin gene in plants (AR 6040, p. 1428, l. 12-15). Adang's testimony suggests that all their knowledge about poly-A tails and poly-A sites, their concept of removing or modifying poly-A sites from Bt toxin genes, and the basis therefor, were written down in Dr. Murray's laboratory notebook (AX 101B) and Dr. Adang's draft abstract for the UCLA symposium talk (AX 106E) (AR 6040, p. 1428, 1. 25, to p. 1430, 1. 2). To the contrary, we find no evidence in either Dr. Murray's laboratory notebook (AX 101B) or Dr. Adang's draft abstract for the UCLA symposium talk (AX 106E) that either Dr. Murray or Dr. Adang knew that the chopped-up RNA found via Dr. Murray's Bt Northerns had poly-A tails or that poly-A sites in Bt toxin genes were causing premature termination of transcription and thus unacceptably low expression of Bt toxin genes in plants. Rather, the closest concept to the invention of Count 2 that we can find expressed in Dr. Murray's lab notebook (AX 101B) and Dr. Adang's draft abstract for his UCLA talk (AX 106E) is their common recognition that, at least for tobacco plants, "Bt may have some kind of premature termination signal . . . where the transcription was

terminating . . . [and] we could . . . site specifically mutagenize the premature termination region of the <u>Bt</u> gene"

(AX 101B) and "for efficient expression of this toxin in tobacco plants the coding sequence must be modified to eliminate premature termination of transcription" (AX 106E, p. 2). That concept does not recognize all the features and/or limitations of Claim 1 of Adang's involved patent or corresponding Count 2. Specifically, we find in these passages no recognition of the need for plant-preferred codons.

According to Fact 36, Drs. Adang and Murray "reached the conclusion that the <u>Bt</u> DNA sequence was causing instability of the mRNA in plants" (AB 10, Fact 36). Fischhoff does not appear to deny the truth of the statement. Nevertheless, even assuming its truth, that conclusion does not support its alleged conception of the invention of Claim 1 of Adang's involved patent or Count 2 prior to December 12, 1986. Adang cites the following testimony of Dr. Adang in the District Court of Southern California in support of Fact 36 (AR 0089, 1. 25, to AR90, 1. 12):

Liz did northern blots that identified truncated transcripts in Bt transgenic plants. So Liz was aware of the problem. And as I recall, Liz and I both started chatting about and discussing what might be wrong.

. . . I almost think we had sort of a mutual coming together of our backgrounds and insights to come up with

this solution to improve codon, preferred codons and codon frequency in genes.

Here, Dr. Adang refers to his chats with Dr. Murray regarding the solution to improve the number and frequency of plant-preferred codons in Bt gene sequences. The best Dr. Adang could do in the District Court of Southern California was cite the same documentary evidence he previously cited, i.e., Dr. Murray's lab notebook and the draft abstract for his UCLA talk (AX 101B; AX 106E), and prior knowledge in the art. For example, in California, when asked if there was anything which helped him to date his conversations with Dr. Murray, Dr. Adang testified (AR 0092, 1. 6, -0093, 1. 2; emphasis added):

[W]hat has helped me some in terms of focusing in on the date of that time was [sic] - an understanding of when, about when Liz's northern blot results were obtained. My recollection of searching the Bt gene for various sequences that I thought, perhaps, might be deleterious to expression. And so there's sort of these events of data we were seeing, my recalling doing various computer searches. And then knowing, you know, my interaction with Liz and remembering sort of these discussions at that period. So it kind of fits in with, I think, very well with that late 1985 period of time.

Q. When the idea was conceived, either by you or by Elizabeth Murray, of increasing the number of preferred codons in the native Bt gene to improve expression, did you or she write the idea down?

THE WITNESS: I don't recall. .

Dr. Adang's California testimony continued (AR 0094,

1. 8, - AR 0095, 1. 22):

- . . . I saw evidence of my steps towards modifying Bt genes for improved usage and frequency as well as number of preferred-plant codons.
- Q. And what evidence did you see?
- A. . . . I saw data on codon usage, analysis of plant genes. I saw analyses of Bt codons and Bt gene codon usage. And I also recall seeing analyses of that led to design and synthesis of synthetic Bt gene, designs along those principles of codon preference and codon usage.
- Q. When did work on codon usage tables begin?

THE WITNESS: Well, it depends what one means on work on codon usage tables. You know, in the - I was aware of codon usage tables in the literature, and you know, in my own work, as a plant molecular biologist in the early 1980s. And so aware of these published literature values on plant codon usage.

And later Liz began, along with her colleagues, the actual construction of the codon usage tables, examples that are presented in the patents.

- Q. Do you know why Elizabeth Murray began construction of her own codon usage tables rather than simply relying on the codon usage tables in the published literature?
- A. . . . My sort of kind of my speculation on it, kind of my recollection, would be that Liz wanted a more complete representation of plant genes that were available in deposited sequences in the nucleotide sequence databases at the time. She just wanted a better survey of genes to incorporate into her tables.

Specifically relating to the need for a more complete codon usage table to enable persons skilled in the art to use the

concept of increasing the number of plant-preferred codons in the native Bt gene in order to improve expression, Dr. Adang testified (AR 0096, 1. 21, - AR 0097, 1. 2; emphasis added):

[M]y opinion . . . is that we could have taken the codon usage tables available at the time. It perhaps would have been riskier than what we actually did in terms of trying to - not trying to, but compiling broader tables.

Asked when Elizabeth Murray began work to construct her own codon usage tables (AR 0098, 1. 9-10), Dr. Adang testified (AR 0098, 1. 12-22) (emphasis added):

When Liz - it's difficult for me to say the exact time when Liz started to construct her own codon usage tables. You know, my recollection of that, '86 - my recollection is that it was in '86 when she came to me and we discussed assembling of plant codon usage tables.

But she perhaps had been doing that before, you know, on her own. Then she came to me with this idea of bringing it into sort of a broader part of the project and getting some assistance with it.

Immediately thereafter, Dr. Adang testified regarding the relationship of codon usage tables to the invention claimed in Adang's involved patent (AR 0104, 1. 25, - AR 0105, 1. 11):

- Q. You mentioned in an earlier answer, about the same breadth as codon usage tables, an analysis of plant genes. And I wanted to ask you, was the analysis of plant genes something different from the codon usage tables?
- A. An analysis of plant genes would include but not be limited to codon usage.

Dr. Adang provided the following additional testimony (AR 0107, l. 19, - AR 0108, l. 0111, l. 5) (emphasis added):

Q. All right. Now, can you explain to me, Dr. Adang, if all you need to do is look at codon usage and codon frequency and design a gene accordingly, and that would work, why it was that there was this delay between 1985, when you had the idea of modifying the native Bt gene to add a greater number of plant-preferred codons, and perhaps as late as 1987, when the first Agrigenetics-constructed codon usage table had been developed? Why did you wait so long?

THE WITNESS: . . . Well, we knew - we knew we were getting truncated RNA, which was a disappointment. We knew we were getting low levels of Bt protein expression. . . We thought that we could pin down regions that would, save us money, save us time, so that we could, you know, we could define certain regions that would be our first regions to change along the lines of codon, preferred codons and codon frequency. So we really thought we were taking a shortcut by just doing those fatal, quick experiments. And so we thought we could get to building a gene faster that way.

We also had constraints in the program of needing a slightly improved expression very quickly. Okay? In that Agrigenetics was going through a period of instability, where the partnership was expiring, Lubrizol was acquiring us we were faced with the need to get plants a little bit better, a little bit faster. And so I would say that that detracted from, or rather - not detracted. I think that whenever you're organizing a program, you're choosing priorities. And one of our priorities in addition to - so that the gene fixing priority, was also just enhancing the expression of wild type genes a little bit so that we could satisfy the upper management.

- Q. In the effort -
- A. . . . To summarize, we had these sort of practical factors of meeting short-term deadlines, and then <u>we also</u> had this belief that we could find the region that would be most easily fixed.

You know, I think that there was a time when we really needed codon usage tables to be put to use. Okay? We felt

- that . . . we were going to pin down the region of the gene that should be fixed first. And as soon as that was available I mean, if we had pinned down a region, that would have moved the timeline to a much earlier time upon when we could commence sort of gene construction and actually using the codon usage tables for our purposes.
- Q. What kind of region were you looking for that could be most easily fixed?
- A. Well, we were looking for a region that caused RNA instability.
- Q. This would be separate and apart from the absence of plant-preferred codons?

THE WITNESS: I think our search for the region of - regions of causing, causing RNA instability, yeah, was somewhat distinct from the codon usage at that point. We focused, for example, on the region at 1.7 KB because that's where we knew the RNA was truncated that we'd seen in Bt plants. So we had some physical evidence there that by itself would help us to target that region as identifying a region of instability.

Having testified that the "search for the region . . . causing RNA instability . . . was somewhat distinct from codon usage" (AR 0110, 1. 22-25), Dr. Adang's description of "what type of work was done to define that region" (AR 0111, 1. 12-13) is significant to our consideration of whether or not Adang exercised reasonable diligence toward reducing the invention of Claim 1 of Adang's involved patent, and thus Count 2 of this interference, to practice.

Claim 1 of Adang's involved U.S. Patent 5,380,831 includes the step of "modifying a portion of said coding sequence [of a \underline{Bt} gene which encodes an insecticidal protein toxin] to yield a

modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence" (Claim 1 of Adang's involved U.S. Patent 5,380,831). Dr. Adang testified as follows (AR 0111, 1. 21, - AR 0112, 1. 16):

A. There's a series of experiments based on constructing a series of gene deletions of the natural Bt genes. There's a series of experiments directed towards transgenic expression systems. The most extensively worked with was electroporation. We also contemplated, designed some experiments with heli cell extracts. We then eventually had a series of experiments with using heat shock promoters and constructs.

.

At some point also we then began to do experiments . . . testing Shaw Kamen sequences in transgenic expression systems. So each of those experiments were for the purpose of identifying the gene part, region that needed or would benefit from fixing most, would reduce our work load of synthesis. Then we could go and rebuild the gene upon codon preference and codon frequency.

By the series of experiments identified, Dr. Adang had "hoped" (AR 0112, 1. 23, - AR 0113, 1. 8) (emphasis added):

would be sort of the focus. And then . . . we could come back and make these - make codon changes in those regions. . . [Y]ou would have solved the problem of - solved any sort of codon problems and at the same time solved any instability problems. And you get higher expression. But basically it's a way of not having to build a . . . whole gene, upon - and save time and cost.

Dr. Adang was then asked if there came a time when the effort to find a suitable destabilizing region was abandoned

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(AR 0114, 1. 21-22). He stated (AR 0114, 1. 23, - AR 0115,
1. 2):

A. Well, abandoned is a bit untrue in this case. A bit overstated. Okay? We had . . . some experiments on identifying destabilizing regions that we were following up on up until the termination of Agrigenetics . . in August, 1988.

The question we must ask is whether the wealth of experimentation which Drs. Adang and Murray and their associates performed to identify the destabilizing regions of the <u>Bt</u> gene in plants transformed thereby are representative of the exercise reasonable diligence toward reduction to practice of the invention of Claim 1 of Adang's involved patent corresponding to Count 2. Pertinent to the issue is the following question with Dr. Adang's reply (AR 0116, 1. 16-21):

Q. Did you believe that identifying the enhanced destabilizing region would be necessary in order for your invention involving increasing the number of plant-preferred codons in the native Bt gene to work?

A. No.

The work Dr. Murray performed in 1986 and thereafter to create codon usage tables for plants is not the same work Dr. Adang performed no later than 1986 relating to codon usage in Bt genes. Consider the following testimony by Dr. Adang (AR 0119, 1. 17, - AR 0120, 1. 3):

Q. . . . Now, do you remember who it was that did the work relating to codon usage in Bt genes?

.

THE WITNESS: I recall it was myself.

- Q. What did you do?
- A. I recall compiling tables, where I analyzed sequences of Bt genes for patterns of codon usage.
 - O. This was in 1985?
 - A. Yes.

When questioned whether he had seen any documents relating to the work he did in 1985 compiling tables to analyze sequences for <u>Bt</u> genes for patterns of codon usage prior to his deposition, Dr. Adang answered (AR 0121, 1. 2-21):

A. Well, I recall that they were documents, printouts from computer programs that were run to analyze codon usage.

When asked if he had actually developed "a codon usage table for native <u>Bt</u> gene in November of 1985" and used it (AR 0123, 1. 10-11), Dr. Adang testified as follows (AR 0123, 1. 12, to AR 0125, 1. 5):

- A. As I recall, yes.
- Q. Did you make any effort to compare that codon usage table for the native Bt gene with the information available to you regarding codon usage in plants?

A. I looked at codon usage tables that were published for several plant genes . . . \cdot

- Q. As a result of looking at codon usage tables published for plant genes and comparing those to your codon usage table for the Bt gene, did you draw any conclusion?
- A. We concluded that the Bt genes had different codon usage and different preferred codons than plant genes.
 - Q. So the "we" is you and Elizabeth Murray?
 - A. Yes, that's correct.
- Q. . . . Did you identify specific codons in the native Bt gene that occurred more frequently than in plants?
- A. In looking at the native Bt genes, a feature that was striking to me was the number of codons ending in As or Ts at the wobble base position.
 - Q. Why is that striking?
- A. Well, it was striking because that's in opposition to or quite contrast to plant gene. You know, plant genes are rich in Gs and Cs at the third nucleotide position.
- Q. Do you recall drawing any other conclusions as a result of the comparison you made between your codon usage table for the native Bt gene and the published data involving codon usage in plants?
- A. Well, I recall that we took the step of saying Bt genes should be made to look more plant-like by building to include codons preferred and match the usage of plant codons.

Thereafter, when asked about the first time after November of 1985 that Liz Murray, or anyone else, communicated to him a comparison of codon frequencies for <u>Bt</u> genes and codon frequencies for plants (AR 0128, 1. 10-13), Dr. Adang testified (AR 0128, 1. 14-18):

A. I recall in spring of 1987 and continuing into the summer, Liz had proceeded through her compilation of genes and was communicating these results to me and discussing their - some implications regarding Bt.

Next, Adang cites Dr. Elizabeth Murray's testimony

(AR 4152-4156) in Mycogen Plant Science, Inc. v. Monsanto Co.,

No. 96-505 (D. Del. Feb. 5, 1998) (Delaware I) (AB 10, Fact 36).

When asked what the northern analysis indicated to her about Bt expression in plants (AR 4153, p. 449, l. 17-18), Dr. Murray testified (AR 4153, p. 449, l. 19, - p. 450, l. 8):

A. It indicated two things to me. The first thing it indicated was that the Bt expression was very low compared to two other genes that we had put into our - our analysis of the plants.

• • • •

And the RNA that I did see was also shorter than I expected to see. It was about half the size that I expected to see if the full Bt RNA had been made in these plants.

When asked if she formed any ideas and conclusions from the results, Dr. Murray stated (AR 4153, p. 451, l. 25, - p. 452, l. 20):

A. Well, I looked at the results and I believe that it indicated that the coding region of the gene itself was not working in the plant. That the DNA sequence we had added to the plant was from a bacteria. . . . [T]he Bt gene itself wasn't working.

So I believe the sequence of the gene itself was a problem in this plant.

Q. And what did you know about the sequence of the Bt gene at that time?

- A. Well, I knew it was about 70 percent AT and only about 30 percent GC.
- \mathbb{Q} . . . And did you reach any conclusions as to how to solve the problem?
- A. I believe that we should go through and analyze the Bt gene very carefully and try and identify sequences that were specifically contributing to this. And since the gene itself was very AT-rich, you know, some of those sequences could be identified and we could remove them and improve the gene's ability to be used in the plant.

When asked if she discussed the results and the ideas arising and conclusions she drew therefrom with Dr. Adang, Dr. Murray testified (AR 4154, p. 453, l. 1, - p. 455, l. 5) (emphasis added):

A. I remember one particular discussion in November 1985. And in this discussion, I went up to Mike's office with my results, with my X-ray films of the blots, and I talked to him about some experiments that I wanted to run, some more experiments, to try and identify what the problem was with the Bt gene. And I told him my idea at that time, that the coding sequence itself of the Bt gene was the problem and that we would have to go through and modify the coding sequence of the Bt gene in order to improve its expression.

And Mike was very familiar with the insecticidal properties of the Bt protein. And I really wasn't as familiar with that.

So he said to me if we change even one amino acid, or delete even one amino acid, it may no longer by the same Bt protein.

It may now act on different insects. And I've done experiments making the Bt gene shorter and it loses its toxicity. So we have to keep the whole section in there in order for it to work.

And I replied back to him that I knew a way we could do that, because I knew that the - the coding usage of the Bt gene must be different than the typical coding usage of a plant gene.

I was very familiar with the - what a typical plant gene looked like. And from looking at the sequence of the Bt gene, which I had done by that time, I was very aware that it didn't look like a plant gene.

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Dr. Adang and I thought that seemed like a reasonable solution to the problem, but he said, well, do we need to rebuild the whole gene, or is there some section of the gene that we can focus on to rebuild immediately, to get some kind of improvement in the sequence.

.

I pointed out that the very short RNA's that I had been seeing, that were about half as long in the Northern Blots, those might be a clue to what one region we might want to fix was: That if we could identify the sequences that were near the end of that particular short RNA, maybe they would be the sequences which were causing some of the problems.

I still thought the sequences that were near there would be fixed by changing them to reflect the codon usage of the plant gene.

Immediately, thereafter, the questions posed to Dr. Murray in Delaware I focused on her prior knowledge that "codons with C and G in the second and third position" and "polyadenylation signals" in plant genes (AR 4154, p. 455, l. 7, - p. 456, l. 16):

Q. . . . Doctor, at this time, had you had occasion to look at the usage of codons with C and G in the second and third with regard to their usage in plants?

A. In my dissertation, I had read the article by Lysette and when I was summarizing that discussion in my dissertation, I repeated the analysis results that Lysette had found and I said that the XCG dinucleotide with C in the second position and G in the third position was avoided and very rare in most dicot plant genes.

And my . . . gene was from a dicot plant gene. And I had also observed that it followed that rule.

- Q. And in November of 19, or by November of 1985, had you also considered the use of polyadenylation signals in plant genes?
- A. Yes. The very short RNA that I saw in the Northern Blots was a polyadenylated RNA. And I felt that perhaps it was a short RNA because the polyadenylation signal that's present in the BT RNA might have caused it to be shortened and polyadenylated in the wrong place.

Normally, bacteria don't polyadenylate their messages, so they don't have any force that causes them not to develop polyadenylation sequences in there.

- Q. And did you propose a program for, or a method of modifying the entire gene to Dr. Adang?
- A. Well, we talked about resynthesizing the gene to improve codon usage. That we could take artificial sequences of DNA that had been made in the laboratory and make short regions and completely rebuild the gene.

And we had heard that this was possible, and that that might be required in order to get a bacterial gene to work in a plant. We thought that might be required in this case.

Then, Dr. Murray was asked how long resynthesis of a toxic protein <u>Bt</u> having improved codon usage would take. Dr. Murray testified (AR 4155, p. 457, l. 10, - p. 460, l. 6):

A. In order to make the shortest possible gene that we knew made the toxin part of the gene, we knew it would take over 1800 bases to make it.

And the DNA's you make on the oligosynthesis machine are single-stranded, so you'd have to multiply that by two. Then you'd have to build some overlaps in so they could be assembled.

.

- Q. And did you make some kind of an estimate of how long it would take to do that, then, if you were to make an 1800 base pair long DNA?
- A. Well, I think it would take me over 500 days if it was just me working.
- Q. And did you discuss the length of that project with Dr. Adang?
- A. Well, Mike and I did talk about that and we thought if we could get some kind of incremental improvement, by improving some shorter region of the gene, such as polyadenylation regions, that that would be an advantage, because we were really kind of a small company, and we wanted to have some incremental improvements. We might be able to go back and make another improvement and then another improvement and add those on together, to improve the overall performance of the gene.
- Q. What approach did you decide to use for modifying the gene?
- A. We decided to use the approach for looking for a specific region in the gene to modify. But we agreed that the way to modify it was to change the codon usage and balance the ratio of AT to GC, to being more like that of a plant, and to retain the amino acid sequence of the Bt gene and change it to the codons preferred by the plant. The frequencies most commonly used by the plant.

. . . .

Q. And can you describe for me what you did?

- A. I started in November 1985. I took the shorter RNA's that we had purified from the transformed tobacco plants and I set about doing a set of experiments to try and identify exactly what sequences were at the end of the short RNA's. And those kinds of experiments are called nucleus [sic, nuclease?] protection.
- Dr. Murray proceeded to describe the kind of experiments which were performed and the periods of time over which they were performed. In example (AR 4156, p. 461, l. 22, p. 462, l. 4):
 - Q. When did you start working on those nuclease protection assay experiments?
 - A. I started working on these in November 1985.
 - Q. And how long did they continue?
 - A. Well, I worked on them intermittently, doing other experiments along the way, through August of 1987. And I still continued to try and complete some experiments after August 1987 until January 1988.

For other examples, see the following testimony (AR 4156, p. 462, l. 7, - p. 463, l. 3) (emphasis added):

- O. What else did you do?
- A. Well, I continued to do some Northern experiments, because I was looking for RNA to do the nuclease protection experiments with. And the nuclease protection experiments were designed to look at the short RNA's and they weren't always present in the transformed plants.

And I continued to work on a new technique that I and another scientist at Agrigenetics were developing so I could do more rapid analysis of the Bt genes in a plant cell. And the technique is called electroporation.

A. I was very interested in developing electroporation so that I could use it to analyze the Bt genes themselves.

Dr. Murray considered any time spent developing electroporation well-spent because (AR 4156, p 464, l. 8-15):

[W]e felt there was a huge advantage to doing this kind of experiment in electroporation, because if I had to make a remodeled Bt gene of some kind, and put it into a plant, that would take three months, four months, possibly even longer until I had anything to analyze, whereas if I was able to take the same piece of DNA and put it into a plant cell, I could get the result out in one hour to two days.

Interestingly, we find from her testimony in Delaware II that Dr. Murray's interest in developing electroporation arose at least in part because of Dr. Murray had doubts that polyadenylation sequences were causing the shorter RNA sequences and proposed alternative solutions to the problem (AR 4156, p. 464, l. 25, - AR 4157, p. 466, l. 1) (emphasis added):

- Q. Doctor, you said if you made some kind of a modified DNA. What type of modified DNA did you expect that you would be able to make based upon this set of experiments you were doing with the nuclease protection assay?
- A. Well, I felt that one way to analyze the nuclease protection assays was to go in and change the sequences and remove the polyadenylation sequences.

I also thought the shorter RNA's might have occurred due to some other mechanism besides polyadenylation. But that would have been a completely new mechanism.

And I also thought it might just be the coding region of the gene was not going to be translated very well by the plant gene.

And one of the modifications that we did to test this kind of experiment was called a deletion analysis.

- Q. What is deletion analysis?
- A. In deletion analysis, you take a regular gene and you make it shorter and shorter and shorter by digesting away more and more of the gene. And then you take those different size deletions and you sequence them so you know exactly how big they are. And then you can do your analysis with those, to see if the shorter genes act differently than the longer genes.
 - Q. And why were you doing those assays?
- A. Well, I was doing those assays because the nuclease protection assay wasn't immediately revealing where the end of the short DNA was. And much of the time I didn't even have any short RNA to analyze.

So I felt that if I could modify these shorter genes and make them shorter and shorter, I eventually get to a point where the gene worked better and then I could start rebuilding from that end.

Dr. Murray testified that the experimental procedures in the use of electroporation which she worked to develop finally yielded reproducible results and were suitable for her to use in October of 1986 (AR 4157, p. 467, l. 4-8). Accordingly, she testified (AR 4157, p. 467, l. 9, - p. 468, l. 7) (emphasis added):

From October of '86 until about January or so, February of 1988, I worked on electroporation of various Bt genes and worked first to get the technique to work so we could make RNA out of the cells and then I worked on doing my analyses, using electroporation.

Q. Did you ever do any work on analyzing the Bt sequence, other than what you did in the latter part of 1985?

- A. Yes.
- Q. What kind of work did you do?
- A. I would scan the sequence, looking for polyadenylation regions. And as we would read the literature, we'd look for new sequences like that.

I did analyses of the Bt coding sequence to get these shorter pieces of DNA so I could do my mapping experiments.

And we would just look at the sequences and compare them with other sequences that were being described in the literature.

In 1985 new genes were being sequenced and this was a great time for new material being available. And we would read the literature and look at the Bt gene and see if there was anything interesting to compare it with, with what was reported in the literature.

When asked if she spent time preparing codon usage tables while at Agrigenetics, Dr. Murray testified (AR 4158, p. 470,

1. 11, p. 471, 1. 22) (emphasis added):

A. I started working on codon usage tables that I would generate myself. I started learning how to use the software in late spring and early summer of 1987. And I needed to know how to use two pieces of software. I needed to use a software to generate the codon usage tables and then I needed to get the sequences of the genes to enter into the codon analysis software.

So I started collecting the sequences of the genes to put into the codon analysis software throughout the summer of 1987, kind of intermittently. And then, in August 1987, I did codon analysis with the sequences that I had collected.

And that's in my notebook on August 27th, 1987.

We started trying to figure out exactly how to build that gene in August 1987, and then we worked on the synthesis of the oligoes and had a plan drawn up by kind of winter and spring of 1988. I think around March 1988 they had a plan finalized for how to do it. And then they started synthesizing to oligoes for it.

Well, . . . I was pregnant and my baby was due March $30^{\rm th}$, and so I - there was a period of time where I worked only on codon analysis and wasn't working so much in the lab. And then I had two months of maternity leave.

So, I wasn't working on the exact design of rebuilding the gene.

The Declarations of Michael J. Adang (AR 6876-6882) and Elizabeth E Murray (AR 6883-6889), filed as Exhibits 36 and 35 respectively in Delaware I, tell a story generally consistent with the inventors' testimony. Dr. Adang declared that the following points were worthy of consideration:

- (1) Dr. Adang declared that his efforts to reduce the invention to practice (AR 6877, para. 4)
 - . . . focused on DNA sequence analysis of Bt genes to identify the regions in the Bt gene sequence requiring modifications using plant preferred codons, designing the DNA sequence of the synthetic Bt gene, and overseeing and participating in the construction of the synthetic Bt gene. These efforts are recorded as computer printouts, and pages from several laboratory notebooks[;]
 - (2) Dr. Adang declared (AR 6877, para. 5):

I prepared a draft of an abstract for a meeting which reflects the conception directed to Bt gene modification methods which I and Dr. Murray had previously made. . . . This draft was prepared on November 6, 1985 Our conception of Bt gene modification methods which included

altering the coding sequence of a Bt gene to make that Bt gene more plant-like by introducing plant preferred codons is reflected in the statement 'It appears that for efficient expression of this toxin in tobacco plants the coding sequence must be modified to eliminate premature termination of transcription.' . . This statement was removed from the abstract before it was submitted because this statement would have revealed our conception regarding our Bt gene modification method to the public at a time when we were diligently reducing that conception to practice.

(3) Dr. Adang declared (AR 6878, para. 6):

Following my conception of the invention with Dr. Murray in November 1985, I sought to determine which sequence differences were present between Bt and plant genes, and the regions of the gene which would require modifications using the methods we had conceived to increase Bt expression in the transgenic plants. I performed several computer analyses of Bt genes, including generating codon usage tables, and determined that the Bt genes had a strong preference for nucleotides A and T in the wobble position, and were generally rich in AT sequences compared to plants

- (4) Dr. Adang further declared (AR 6878-6879, para. 7-9):
- (a) "In December of 1985, I also examined Bt genes for the presence of transcriptional stop sites within the coding sequence which would be modified using plant preferred codons . . [;]"
- (b) "From December of 1985 into January of 1986, I performed sequence comparisons between the cloned Bt genes to determine if consensus sequences were present in the coding regions which would need modification . . . [;]" and
- (c) From March of 1986 through December of 1987, I performed sequence analyses of Bt genes to identify RNA destabilizing sequences which would need to be reduced and/or eliminated to enable increased Bt gene expression. In addition, I continued sequence analyses and comparisons of the Bt genes. Other sequence analyses to locate RNA destabilizing sequences in Bt genes were performed by other Agrigenetics scientists. These efforts are reflected in . . . computer searches . . ."

- Dr. Murray's declaration is a timeline of her efforts from November 1985, until June 1988.
 - Nov. 12, 1985 Feb. 10, 1986 and Aug. 15, 1986 Jan. 7, 1987: nuclease protection assays on RNA derived from Bt transformed tobacco plants; attending scientific meetings; electroporation experiments; generating codon usage tables (AR 6884, para. 5);
 - Feb. 25, 1986 July 3, 1986 and Nov. 6, 1986 Mar. 9, 1988: originated the concept of electroporation as a technique to quickly monitor RNA expression levels and transcript size; several months to optimize electroporation conditions (AR 6885, para. 6);
 - May 26, 1987 Aug. 26, 1987: experiments as needed to design a probe for nuclease mapping experiments; began looking for Genbank Sequence Acquisition numbers for plant genes (AR 6886, para. 7);
 - May 4, 1987 Aug. 23, 1987: performed nuclease protection analyses and electroporation analyses (AR 6886, para. 8);
 - Aug. 26-28, 1987: preparation and presentation at meeting (AR 6886, para. 9);
 - Aug. 27, 1987 June 28, 1988: work obtaining gene sequences for generating and compiling codon usage tables (AR 6887-6888, para. 11):

This work involved selecting the sequences of highly expressed plant genes from the Gen Bank database and from published scientific articles, confirming their sequences, and inputting the data into the computer. Since the GenBank sequence was constantly updated, I continued compiling the codon usage tables to be as comprehensive as they could be. To be more efficient, I enlisted the help of Mary Eberle and several secretaries to update the computer files while I was performing the experiments to identify the regions in the Bt gene sequence to modify first . . . My notebook pages only reflect records of when I spent the entire day working on the codon usage tables.

- when I worked on the tables in my laboratory notebooks. On many days, which are not recorded, I spent a few hours entering sequence data into the computer for the codon usage tables. Some of the codon usage tables are reflected in computer printouts . . . The preparation of the codon usage tables was carried out without any significant gaps or delays.
- Jan. 19-21, 1988 Feb. 5, 1988: continued screening Bt constructs using electroporation (AR 6888, para. 12);
- Feb. 5-26, 1988: analysis of Bt expression by Norther blots; planned upcoming Bt experiments; met with Ann Merlo to discuss future Bt experiments; and compiled codon usage tables (AR 6888, para. 13); and
- Apr. 15, 1988 June 13, 1988: maternity leave.

In addition to the foregoing testimonial and documentary evidence Adang specifically cites, Dr. Adang testified that the collective evidence supports Adang's position that it was first to conceive of the invention of Claim 1 of its involved patent corresponding to Count 2 and exercised reasonable diligence toward reduction to practice (AB 12, Fact 43). However, Adang cannot point to any evidence which explicitly describes the inventive concept defined by Claim 1 of Adang's involved patent corresponding to Count 2 (AR 4614, p. 1729, l. 3-20):

- Q. . . . Now, Dr. Adang, when you came up with this idea in the fall of 1985, did you write down this idea?
- A. I have not found any documents that explicitly state all this, the entire context of this idea. What I have found, and what we talked about here, is there is evidence saying that we knew the <u>Bt</u> RNA was truncated. We knew the <u>Bt</u> gene was AT-rich. We knew that the <u>Bt</u> genes preferred AT codons. We knew we were getting some type of termination

of transcription. And we knew how to fix it, through mutagenesis or building up stretches of the whole gene.

- Q. Do you believe that you have any documents that show that you and Dr. Murray did come up with this idea in November of 1985?
- A. I think all those documents collectively that I just mentioned, the RNA analysis, the computer searches, the AT-richness, the UCLA abstract, they all support, corroborate this invention of Dr. Murray's and mine.

In that vein, Dr. Adang's subsequent testimony is most informative. When asked how he proceeded after he and Dr. Murray "had conceived of the idea in November of 1985" (AR 4614, p. 1729, l. 21-23), Drs. Adang and Murray testified that they were sidetracked in their endeavor to reduce that idea to practice (AR 4614, p. 1729, l. 24, to p. 1730, l. 9):

A. Well, we discussed how to approach this problem, how to go about fixing the Bt gene by replacing these AT-rich codons with plant-preferred codons.

We thought that the quickest way to change the Bt gene so it was highly expressed was to go into the gene and to find those stretches of the Bt gene that were causing the greatest problems for this - greatest problems causing lower expression. So we designed a series of experiments to try to identify the worst regions of the Bt gene, that we could then go back and fix, putting in plant preferred codons.

(iii) Findings

Having considered the totality of the evidence before us, we find that prior to December 12, 1986:

(1) Adang suspected some kind of premature termination of transcription because Dr. Murray's record of analysis of

tobacco plants, which had been transformed by <u>Bt</u> DNA encoding insecticidal protein and expressed low levels of <u>Bt</u> toxin, reported truncated RNA sequences much shorter than expected, (AX 101B; AR 4153).

- (2) Drs. Adang and Murray suspected that a <u>Bt</u> DNA sequence encoding <u>Bt</u> toxin could be efficiently expressed in tobacco plants if it were modified to eliminate the cause of premature termination of transcription in the plants (AX 106E).
- (3) Drs. Adang and Murray knew that a codon usage table had been developed by Dr. Adang (AR 0123-0125) and that a limited amount of codon usage, preference, and frequency information for plant genes was available (AR 0094-0097).
- (4) Based on the limited amount of codon usage, preference, and frequency information for <u>Bt</u> and plant genes available, Drs. Adang and Murray concluded that <u>Bt</u> genes had different codon usage and different preferred codons than plant genes (AR 0123-0125).
- (5) Drs. Adang and Murray knew that the codon usage, preference, and frequency data for <u>Bt</u> and plant genes available for predicting design modifications of <u>Bt</u> DNA encoding insecticidal protein for efficient expression

- in plants was incomplete and that the use of that data for their purposes was risky (AR 0094-0097).
- (6) Drs. Adang and Murray elected to pin down a region of the \underline{Bt} gene that could be most easily fixed and should be fixed first (AR 0107-0108).
- (7) Drs. Adang and Murray were looking for a region that caused RNA instability (AR 0107-0108).
- (8) Drs. Adang and Murray considered their "search for the region of . . . [the <u>Bt</u> gene] causing RNA instability . . . somewhat distinct from codon usage" (AR 0107-0108).
- (9) Drs. Adang and Murray knew that \underline{Bt} DNA were AT-rich (AR 0123-0125; AR 4153).
- (10) Drs. Adang and Murray knew that plant DNA was GC-rich (AR 0123-0125; AR 4154).
- (11) Drs. Adang and Murray suspected that plants transformed by \underline{Bt} genes encoding toxin would produce more toxin if the \underline{Bt} DNA sequences encoding toxin were modified to make them more plant-like (AR 6039-6040).
- (12) Drs. Adang and Murray knew that one way to make <u>Bt</u> DNA sequences more plant-like was to modify the <u>Bt</u> DNA sequences to include codons preferred by plants and reflect the codon usage of the plant genes (AR 0123-0125; AR 4154).

(AR 4155).

(13) Drs. Adang and Murray decided to approach the problem of poor expression of \underline{Bt} genes in plants by first "looking for a specific region of the gene to modify" (AR 4155).

(14) Drs. Adang and Murray "agreed that the way to modify
. . . [the <u>Bt</u> gene] was to change the codon usage and
balance the ratio of AT to GC, to being more like that of
a plant, and to retain the amino acid sequence of the Bt
gene and change it to the codons preferred by the plant"

Having considered the totality of the evidence before us, we find that, after December 12, 1986:

(15) Dr. Murray started to look for the region or regions that caused RNA instability. Specifically, she "set about doing a set of experiments to try and identify exactly what sequences were at the end of the short RNA's" found in plants transformed by native Bt genes encoding toxin in November 1985 (nuclease protection experiments) (AR 4155; AR 6886) and "worked on them intermittently, doing other experiments along the way, through August of 1987.

And . . . [she] still continued to try and complete some experiments after August 1987 until January 1988" (AR 4156).

(16) From October '86 until January or February or March 1988, Dr. Murray continued to work on a "new technique"

called electroporation that she and another scientist were developing for more rapid analysis of <u>Bt</u> genes in plant cells (AR 4156-4157; AR 6885).

- (17) Drs. Adang and Murray performed experiments directed towards transgenic expression systems based on constructions of a series of gene deletions of natural Bt genes (e.g., electroporation), associated with heli cell extracts, designed for heat shock promoters and constructs, and used to test Shaw Kamen sequences, "each of those experiments were for the purpose of identifying the gene part, region that needed or would benefit from fixing most . . . Then we could go and rebuild the gene upon codon preference and codon frequency" (AR 0111-0112; AR 6884-6886).
- (18) Drs. Adang and Murray "had . . . some experiments on identifying destabilizing regions that . . . [they] were following up on up until . . . August, 1988" (AR 0114-0115).

 (19) "No," Dr. Adang did not "believe that identifying the
- . . . destabilizing region would be necessary in order for . . . [the] invention involving increasing the number of
- plant-preferred codons in the native <u>Bt</u> gene to work"

 (AR 0116, 1. 16-21).
- (20) Dr. Murray "thought the shorter RNA's [identified by Northern blots] might have occurred due to some other

mechanism besides polyadenylation[, <u>i.e.</u>,] . . . a completely new mechanism" (AR 4157).

- (21) Dr. Murray performed deletion analysis experiments because she "also thought it might be the coding region of the [Bt] gene was not going to be translated very well by the plant gene" (AR 4157).
- (22) Dr. Murray continued to compile <u>Bt</u> and plant genes and construct her own codon usage tables for a more complete representation of plant genes into the summer of 1987 (AR 0094-0095; AR 0107-0108; AR 0128; AR 4158).
- (23) Dr. Murray worked to obtain gene sequences for generating and compiling codon usage tables into June of 1988 (AR 6887-6888).

(iv) Conclusions

"Where a party is first to conceive but second to reduce to practice, that party must demonstrate reasonable diligence toward reduction to practice from a date just prior to the other party's conception to its reduction to practice." Mahurkar v. C.R. Bard, Inc. 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996).

"Priority of invention . . . belongs to the first party to reduce the invention to practice unless the other party can establish that it was first to conceive the invention and that it exercised reasonable diligence in later reducing the invention to

practice." <u>Eaton v. Evans</u>, 204 F.3d 1094, 1097, 53 USPQ2d 1696, 1698 (Fed. Cir. 2000).

The facts, as we find them supported by a preponderance of the evidence before us, contradict Adang's argument that it exercised reasonable diligence toward reduction to practice of the invention defined by independent Claim 1 or 11 of Adang's involved U.S. Patent 5,380,831 from a date just prior to Fischhoff's reduction to practice of the invention of Count 2 on December 12, 1986, until September 9, 1988, the filing date of the grandparent application, the benefit of which has been accorded the claims of Adang's involved patent corresponding to Count 2 for purposes of priority of invention. Adang's recognition that premature termination of transcription in plants transformed by native $\underline{\mathsf{Bt}}$ genes had to be eliminated in order to improve plant expression of Bt genes and increase production of Bt insecticidal protein in plants, does not identify the cause of the premature termination of transcription or reasonably suggest "modifying a portion of the coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant" (Claim 1 of Adang's involved U.S. 5,380,831) or "modifying a portion of said coding sequence to yield a modified sequence which has a frequency of codon usage which more closely resembles the frequency of codon usage of the plant"

(Claim 11 of Adang's involved U.S. 5,380,831) as a solution to the problem. Even if we presume that the evidence supports a finding that Drs. Adang and Murray suspected that modification of native Bt DNA sequences encoding toxin to better resemble plantpreferred codon usage would improve expression of the sequence in plants, Drs. Adang and Murray continued to regard the search for the region or regions of the native $\underline{\mathtt{Bt}}$ gene that caused $\underline{\mathtt{Bt}}$ RNA instability in plants as the principal solution to the problem (AR 0107-0108). We find that prior to December 12, 1986, and during the critical period from December 12, 1986, to September 9, 1988, Drs. Adang and Murray were not confident what caused premature termination of transcription in plants transformed by Bt gene sequences; i.e., why they found Bt RNA sequences fewer in amount, if any, and much shorter in length, than would have been predicted in plants transformed by native Bt genes encoding insecticidal protein (AX 101B; AR 4153). Moreover, the evidence weighs heavily against Adang's argument that it had "'a definite and permanent idea of the complete and operative invention, as it is therefore to be applied in practice.' Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) . . . ", Kridl v. McCormick, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997), or so clearly defined the invention that "only ordinary skill would have been necessary to reduce the invention

to practice, without extensive research or experimentation,"

<u>Burroughs-Wellcome Co. v. Barr Labs.</u>, 40 F.3d 1223, 1228,

32 USPQ2d 1915, 1919 (Fed. Cir. 1994).

Between December 12, 1986, and September 9, 1988, Drs. Adang and Murray performed a variety of experiments designed to pinpoint the region of native Bt genes which was causing premature termination of transcription and inefficient production of toxin in plants which had been transformed by native Bt genes encoding insecticidal protein (AX 106E; AR 0107-0108). Drs. Adang and Murray considered their "search for the region of . . . [the native <u>Bt</u> genes] causing <u>RNA instability</u> . . . somewhat distinct from codon usage" (AR 0107-0108; emphasis added)). Thus, we find that a significant amount of experimentation and effort by Drs. Adang and Murray between December 12, 1986, and September 9, 1988, was directed to an invention distinct from codon usage. Moreover, we hold that the concept of "codon usage" is critical to the invention defined by all the claims of Adang's involved patent designated as corresponding to the Count 2. Independent Claim 1 of Adang's involved U.S. Patent 5,380,831 requires modification of Bt DNA sequences encoding insecticidal protein to include codons preferred by plants to reflect the codon usage of the plant genes (AR 0123-0125; AR 4154). Independent Claim 11 of Adang's

involved U.S. Patent 5,380,831 requires modification of <u>Bt</u> DNA sequences encoding insecticidal protein to "more closely resemble the frequency of codon usage of the plant in which it is to be expressed." Even though Drs. Adang and Murray appeared to have "agreed that the way to modify . . . [the <u>Bt</u> gene] was to change the codon usage and balance the ratio of AT to GC, to being more like that of a plant, and to retain the amino acid sequence of the <u>Bt</u> gene and change it to the codons preferred by the plant" (AR 4155), they spent a considerable amount of time doing things "somewhat distinct" from that concept (AR 4156-4157; AR 6885).

Additionally, even though Drs. Adang and Murray suspected that premature termination of transcription and inefficient production of toxin in plants which had been transformed by native <u>Bt</u> genes encoding insecticidal protein were related to differences in codon usage and codons preferred by <u>Bt</u> and plant genes, their suspicions were based on incomplete codon usage, preference, and frequency data. They considered any conclusions drawn therefrom, or inventive concepts based thereon, to be risky (AR 0096, 1. 21, to AR 0097, 1. 2). Therefore, Dr. Murray, with Dr. Adang acceding (AR 0116), expended a considerable amount of time between December 12, 1986, and September 9, 1988, not only looking for regions of the <u>Bt</u> gene which caused RNA instability (AR 0107-0108; AR 4156-4156; AR 0111-0112; AR 0114-0115;

AR 6884-6886), but also compiling <u>Bt</u> and plant gene data and constructing her own codon usage tables for a complete and reliable representation of plant genes (AR 0094-0095; AR 0107-0108; AR 0128; AR 4158; AR 6887-6888).

It appears from the totality of evidence that the reasons Drs. Adang and Murray spent so much time performing experiments related to subject matter "somewhat distinct from codon usage" and continued compiling <u>Bt</u> and plant codon usage data were:

- (1) On or about December 12, 1986, Drs. Adang and Murray suspected that the evidentiary basis for their inventive concept was incomplete and unreliable;
- (2) On or about December 12, 1986, Drs. Adang and Murray were not certain of the cause of, or mechanism causing, shorter RNA's than expected and inefficient production of <u>Bt</u> insecticidal protein in plants transformed by native <u>Bt</u> gene sequences encoding <u>Bt</u> insecticidal protein (AR 4157);
- (3) On or about December 12, 1986, Drs. Adang and Murray "also thought it might be the coding region of the gene was not going to be translated very well by the plant gene" (AR 4157);
- (4) On or about December 12, 1986, Drs. Adang and Murray were not confident that their inventive concept (within the scope of Count 2) was in "sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice."

Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d at 1231, 32 USPQ2d at 1922.

Accordingly, we conclude:

- (A) Presuming Adang conceived of the invention of Claim 1 or 11 of Adang's involved U.S. Patent 5,380,831 corresponding to Count 2 prior to Fischhoff's December 12, 1986, <u>i.e.</u>, conception of the invention of Count 2, Adang has not shown the it exercised reasonable diligence toward reduction to practice of the invention of Claim 1 or 11 of Adang's involved patent from a date just prior to December 12, 1986, to September 9, 1988.
- (B) Adang has not shown that it envisioned or communicated the invention of Claim 1 or 11 of Adang's involved U.S. Patent 5,380,831 corresponding to Count 2 in sufficiently definite and complete form that only the exercise of ordinary skill remained to reduce it to practice, prior to Fischhoff's December 12, 1986, conception of the invention of Count 2.
 - II. Adang's conception of Claim 3 of Fischhoff's involved application and reasonable diligence toward reduction to practice

Claim 3 of Fischhoff's involved application reads (AB 48):

- 3. A method for modifying a wild-type structural gene sequence which encodes an insecticidal protein of <u>Bacillus thuringiensis</u> to enhance the expression of said protein in plants which comprises:
 - a) removing polyadenylation signals contained in said wild-type gene while retaining a sequence which encodes said protein; and

b) removing ATTTA sequences contained in said wild-type gene while retaining a sequence which encodes said protein.

Claim 3 of Fischhoff's involved application comprises modifying the structural gene sequence of a native <u>Bt</u> gene encoding insecticidal protein by both (1) removing polyadenylation signals from the structural gene sequence while retaining a sequence encoding insecticidal protein, and (2) removing ATTTA sequences from the structural gene sequence while retaining a sequence encoding insecticidal protein.

Initially, we presume that the preponderance of the evidence before us supports Adang's allegation that it was first to conceive the invention defined by Claim 3 of Fischhoff's involved application, which alternatively defines the invention of Count 2. Thus, we proceed to the question of Adang's reasonable diligence towards reduction of the invention of Claim 3 to practice. We fail to see how Adang's various experiments and tests designed to determine the cause of premature termination of transcription and inefficient expression of native Bt genes encoding insecticidal protein in plants transformed by said native Bt genes and the region and the regions most responsible for those problems and most easily fixed show that Adang exercised reasonable diligence towards reducing the invention of Claim 3 of Fischhoff's involved application to practice

(AR 0107-0108; AR 0111-0112; AR 6884-6886; AR 4155-4157). Neither Dr. Adang nor Dr. Murray were reasonably certain that mechanisms related to polyadenylation signals and ATTTA sequences caused the premature termination of transcription and inefficient expression of native Bt genes encoding insecticidal protein in plants. Dr. Murray continued to search for other causes because she "thought the shorter RNA's might have occurred due to some other mechanism besides polyadenylation . . . a completely new mechanism" (AR 4157). "Each of those experiments were for the purpose of identifying the gene part, region that needed or would benefit from fixing most . . . " (AR 0111-0112; AR 6884-6886). Dr. Murray testified that, after December 12, 1986, her deletion analysis experiments continued because she "also thought it might be [that] the coding region of the [Bt] gene was not going to be translated very well by the plant genes" (AR 4157). preponderance of the evidence of record leads to the conclusion that Adang did not exercise reasonable diligence toward reduction to practice of the invention defined by Claim 3 of Fischhoff's involved application corresponding to Count 2 for the period beginning just prior to December 12, 1986, until the September 9, 1988, benefit filing date of the grandparent application of Adang's involved patent.

What evidence does Adang cite to the contrary? Adang argues that the evidence shows that Drs. Adang and Murray conceived of the invention defined by Claim 3 of Fischhoff's involved application no later than September 20, 1986.

Adang argues that "Dr. Murray believed that polyadenylation signals were involved with the low <u>Bt</u> expression . . . AR2467: 22-2468:22)" prior to December 12, 1986 (AB 49, Fact 115). To the contrary, Dr. Murray testified in the Southern California infringement case as follows (AR 2467, l. 1, to AR 2471, l. 8) (emphasis added):

- Q. In 1985, Dr. Murray, you didn't know that just by changing just by removing a plant consensus splice site that you would get higher expression of the Bt gene in plants, did you?
- A. <u>I thought it was possible that that would result in higher expression, but I did not know it.</u>
- Q. In fact, there were many things that you thought that would were the source of the problem for expression of the Bt gene in plants at that time; isn't that correct?
 - A. That is correct.
- Q. And in continuing into 1986, you still thought that there were many, many sources of the problem for expression of Bt in plants; isn't that right?
 - A. Many potential sources.
- Q. And as between those potential sources, <u>you didn't know which one was prohibiting expression of Bt in plant</u>, did you?
 - A. That's correct.

- Q. And list tell me all of those things all of the many things that you thought were potential problems as far as Bt expression in plants in 1985 and 1986.
- A. Yes. It occurred to me in 1985 that the Bt gene was not expressing well in plants because it contained a sequence which would lead to the RNA being cleaved [sic, at] some individual site[-]specific recognition site that would lead to RNA turnover. And it occurred to me that the Bt gene would not express well in plants because it contained a polymerase II termination sequence which had not been described very well in terms of sequences in the literature, but which I knew existed.

And that by virtue of the <u>Bt gene not being a plant</u> gene, it inadvertently contained a sequence that polymerase <u>II would terminate at in eukaryotes</u>. So that was another possible explanation.

It occurred to me that there is a normal scanning mechanism used in a plant for recognizing polyadenylation and proceeding with that post transcriptional RNA processing, and that there was some defect in the Bt gene as expressed in plants. The Bt in the bacteria doesn't polyadenylate, as far as I know. And so, you know, it's evolved into being a very AT-rich sequence.

And when you move that AT-rich sequence, then into a plant or some other eukaryote, that there is two steps - two sequences that are recognized. One sequence is recognized and you get cleavage, and then another sequence is recognized and you get polyadenylation following the cleavage. And there is a scanning mechanism for look for - from the 3 prime end, the strongest sequence you might find, and then in a plant you might pick from several and polyadenylate.

So it occurred to me that the Bt gene could be not being stably expressed because it was either cleaving incorrectly, and then a kind of weak polyadenylation signal was being used, and maybe you had to scan down from the cleavage site, or that all these polyadenylation signals that were in there might be a problem as well.

It also occurred to me in 1985 that the Bt gene, because it was AT-rich, simply didn't translate well in

plants because it didn't have the right codon frequency for a plant gene to be expressed well, because I knew any gene that was 70 to 80 percent AT-rich would necessarily have to have a different codon usage than a plant gene which are 50 to - 45 to 55 percent GC-rich depending on, you know, which plant you're looking at.

It also occurred to me that <u>some mechanism that did not</u> allow very good initiation of transcription might occur such that you weren't getting very much transcription at all starting at the very 5 prime end. The whole promoter might not work particularly well.

But on the whole, I tended to think that those were not because of the promoter we had put in front of the Bt gene, the mannopine promoter, but that there might be some regulatory sequences within the 5 prime end of the Bt gene, you know, or anywhere in the Bt gene for that matter such that a, you know, some kind of transcription factor might come in and bind these sequences and block transcription. And I thought that was another possibility.

I - there may have been other possibilities. I did think splicing was a possibility.

We talked about splicing at the group, and I'm not sure I'm the one that first thought of it. I seem to recall other people mentioned splicing to me. And then I say said, I think that could be another reason why we have a truncated RNA.

And then because splicing also involves some kind of site specific cleaving of the RNA, and then you require another mechanism to past the two pieces back together again once you've cleaved out a region. You know, it could be that the cutting part worked well, and then the pasting together part didn't work too well, and so that would lead to RNA turnover as well.

- Q. Have you finished your answer?
- A. Those are the those are the main mechanisms that I can recall at this time.

Based on a more complete consideration of Dr. Murray's testimony, we cannot agree with Adang's statement that, "As early as October/November 1985, Dr. Murray believed that polyadenylation signals were involved with the low <u>Bt</u> expression problem" (AB 49, Fact 115). Nor can we find that Dr. Murray believed that polyadenylation signals were involved with the low Bt expression problem in 1986. Rather, we find that in 1986, Dr. Murray believed it possible that polyadenylation signals were involved with the low Bt expression problem. That possibility is not a description of that part of the invention of Claim 3 of Fischhoff's involved application which requires modification of a wild-type structural gene sequence which encodes an insecticidal protein of Bacillus thuringiensis to enhance the expression of said protein in plants which comprises removing polyadenylation signals contained in said wild-type gene while retaining a sequence which encodes said protein in "sufficiently final form that only the exercise of ordinary skill remained to reduce it to practice." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d at 1231, 32 USPQ2d at 1922. Rather, the evidence shows that Adang's search for the cause of premature termination of transcription and inefficient expression of the native Bt gene encoding insecticidal protein in plants transformed thereby continued well into 1988.

We have little doubt that Drs. Adang and Murray were aware of the existence of polyadenylation signals in Bt toxin genes and discussed the possibility that those polyadenylation signals could be causing the problems they and their colleagues faced prior to December 12, 1987 (AB 49, Facts 116-118). Adang's continuous and varied search for the cause of problems they faced expressing the Bt toxin gene in plants after December 12, 1986, is inconsistent with a conclusion that Adang conceived of the solution, <u>i.e.</u>, the invention defined by Claim 3of Fischhoff's involved application, prior to December 12, 1986, and exercised reasonable diligence toward its reduction to practice. The preponderance of evidence before us indicates that, prior to December 12, 1986, and continuing well into 1988, Adang did not have "'a definite and permanent idea of the complete and operative invention [of Claim 3 of Fischhoff's involved application], as it is therefore to be applied in practice.' Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) . . .", Kridl v. McCormick, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997). Nor did Adang so clearly defined the invention of Claim 3 of Fischhoff's involved application prior to December 12, 1986, that "only ordinary skill would have been necessary to reduce the invention to practice, without extensive research or experimentation," Burroughs-

Wellcome Co. v. Barr Labs., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). In short, Adang's case for priority of the invention defined by Claim 3 of Fischhoff's involved application is weak. As said in Burroughs-Wellcome Co. v. Barr Labs., 40 F.3d at 1227-28, 32 USPQ2d at 1919 (emphasis added):

Conception is the touchstone of inventorship, the completion of the mental part of invention. Sewall v. Walters, 21 F.3d 411, 415, 30 USPQ2d 1356, 1359 (Fed. Cir. 1994). It is "the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986) (citation omitted). Conception is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation. Sewall, 21 F.3d at 415, 30 USPQ2d at 1359. . . .

Thus, the test for conception is whether the inventor had an idea that was definite and permanent enough that one skilled in the art could understand the invention; the inventor must prove his conception by corroborating evidence, preferably by showing a contemporaneous disclosure. An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. See Fiers v. Revel, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1989) These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention.

We recognize that, as stated in <u>Burroughs-Wellcome Co. v.</u>

<u>Barr Labs.</u>, 40 F.3d at 1228, 32 USPQ2d at 1919-1920, "an inventor need not know that his invention will work for conception to be

complete. Appelgate v. Scherer, 332 F.2d 571, 573, 141 USPQ 796, 799 (CCPA 1964). . . . An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception. MacMillan v. Moffett, 432 F.2d 1237, 1239, 167 USPQ 550, 552 (CCPA 1970)." On the other hand, the court also said, Burroughs-Wellcome Co. v. Barr Labs., 40 F.3d at 1229, 32 USPQ2d at 1920:

A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

Here, Adang's course of diverse experimentation, part of a strategy designed to identify the regions of <u>Bt</u> genes encoding insecticidal protein responsible for premature termination of transcription and inefficient expression of the <u>Bt</u> genes in plants, did not lead to a reduction to practice of an invention of Count 2 prior to September 9, 1988 (AB 50). By January 1988, Adang's admitted "lack of quick success in their original strategies" (AB 54-55) had resulted in an accumulation of information, much of which was acquired after December 12, 1986. The accumulated information was sufficient to support a patent application directed to certain of Adang's various possible alternative solutions to problems which Adang had recognized as possible solutions prior to December 12, 1986 (AB 50-51).

However, we find that Adang's uncertainty as to the cause of premature termination of transcription and inefficient expression of Bt genes encoding insecticidal protein in plants, as evidenced by Adang's continued lack of success and accompanying accumulation of more complete information between December 12, 1986, and September 9, 1988, suggests that none of Adang's pre-December 12, 1986, possible solutions to the problems they had encountered expressing Bt genes encoding insecticidal proteins in plants represented a definite and permanent idea of a complete invention of Claim 1 or 11 of Adang's involved patent or Claim 3 of Fischhoff's involved application.

More importantly, Adang's evidence as a whole does not establish that it had recognized removal of ATTTA sequences specifically and polyadenylation sites generally from the native Bt gene encoding Bt toxin as a definite and permanent solution to the problems they found expressing the native Bt gene in plants. Adang attempts to remedy the shortcomings of its case for priority of the invention defined by Claim 3 of Fischhoff's involved application by reference to published prior art and knowledge of the publications in the art prior to December 12, 1986. This remedy is hard to swallow.

First Adang cites an article by Dean et al., <u>Nucleic Acids</u>
Res., citation illegible (AX 102F), which is said to have been

published in March 1986 and describe "multiple polyadenylation sites in mRNA transcripts of several plants" (AB 49, Fact 119). Even if we accept the alleged publication date as fact, and presume that the publication in fact describes "multiple polyadenylation sites in mRNA transcripts of several plants" as stated (AB 49, Fact 119), the inventors thereafter testified that they were not certain that polyadenylation signals were responsible for the premature termination of transcription and inefficient expression of native <u>Bt</u> genes encoding insecticidal protein seen in plants (AR 4156, p. 464, l. 25, - AR 4157, p. 466, l. 1).

Second, Adang relies on the prior publication of Shaw and Kamen (hereafter Shaw), "A Conserved AU Sequence from the 3' Untranslated Region of GM-CSF mRNA Mediates Selective mRNA Degradation, Cell, Vol. 46, pp. 659-667 (August 29, 1986) (AB 49, Fact 120). According to Adang (AB 49-50, Facts 121-125), soon after becoming aware of the publication's disclosure, Dr. Adang "was impressed with the effect those sequences had on destabilizing messenger RNA" (AR 0252, l. 11-19), Dr. Murray was "very excited about it" (AR 2483, l. 14-18), and Dr. Adang and colleagues at Agrigenetics began searching Bt gene sequences for ATTTA sequences (AR 2483, l. 14-18; AR 6878-6879; AX 1061; AR 0371-0374; AX 34C). Adang argues (AB 50, Fact 124) that

Dr. Adang found that <u>Bt</u> DNA contained the ATTTA sequences Shaw found problematic to transcription (AR 0372-0374). Adang especially relies (AB 50, Fact 125) on a memorandum he drafted to Dr. Murray on September 20, 1986 (AR 0372-0374; AX 34C). The handwritten memorandum, dated "9/20/86" and initialed "MJA" reads, in part (AX 34C):

Liz,

Here are the searches of 4 \underline{bt} genes for ATTTA in the coding sense direction. It seems that one needs to search plant 3' untranslated regions for AU sequences to get a feeling for their role in plant mRNA stability.

As you can see all 4 genes have AUUUA sequences in the central 1/3 of the gene.

It is interesting that cycloheximide increased RNA to normal levels. Can we do this w/ Bt constructs in protoplasts?. . . .

We fail to see how Shaw's disclosure remedies the defects in Adang's case. The evidence of record shows that Adang did not understand and could not explain why Bt gene sequences in plants were not being efficiently expressed in plants. The record shows that there are significant differences between genetic sequences, codon usage, etc. in Bacillus thuringiensis and plants, not to mention the differences among various plants themselves. These differences may be the cause of the problems Adang aimed to solve. Regardless of how impressed or excited Drs. Adang and Murray were by the teaching of Shaw's publication prior to

December 12, 1986, the fact is that Shaw dealt with the stability of mRNAs of certain lymphokines, cytokines, and protooncogenes in animals (AX 121L, Shaw's Summary). We find little, if any, difference in the certainty with which Adang explained the evidence of premature termination of transcription and inefficient expression of <u>Bt</u> DNA sequences encoding insecticidal protein in plants and planned future experimentation before and after Drs. Adang and Murray were "impressed" and "excited" by Shaw's disclosure.

Adang alleges (AB 50, Facts 123-125), and the evidence appears to show, that Dr. Adang searched for and found ATTTA sequences in Bt genes prior to December 12, 1986 (AR 6878-6879, para. 9; AX 106I; AR 0371-0374; AX 34C). Nevertheless, the same evidence shows that Adang's efforts to identify any and all possible RNA destabilizing sequences continued through December of 1987. Dr Adang declared (AR 6878-6879, para 9; citations omitted (see AX 106I for computer searches from March 1986 though December 1987)):

From March of 1986 through December of 1987, I performed sequence analyses of Bt genes to identify RNA destabilizing sequences which would need to be reduced and/or eliminated to enable increased Bt gene expression. In addition, I continued sequence analysis and comparisons of the Bt genes. Other sequence analyses to locate RNA destabilizing sequences in Bt genes were performed by other Agrigenetics scientists. These efforts are reflected in the following computer searches: . . .

Deposed in Mycogen Plant Science, Inc. v. Monsanto Co.,
No. 96-505 (D. Del. Feb. 5, 1998), Dr. Adang testified as follows
relative to a computer search document generated in September of
1986, identified as MC035038 (AR 0371-0372) (emphasis added):

- Q. About a third of the way down the statement appears, "Search of hd73.trunc, ATTTA." Do you see that, sir?
 - A. I do.
- Q. This is a reference to a search which you made of the nucleotide sequence in a native Bt gene to see if that sequence contained the sequence ATTTA; correct?
 - A. Correct.
- Q. And the reason you performed the search was because you believed at the time that the ATTTA sequence was potentially a destabilizing sequence in the Bt gene that interfered with expression of the Bt gene in plants; correct?
- A. Yes. With, you know, <u>emphasis on the term</u> "potentially," yeah. Yes.

In the same deposition, Dr. Adang testified (AR 0374; emphasis added):

Q. As a consequence of these searches, is it true that the ATTTA sequence was removed from the gene, the design of which is described in the specification of the '600 and '862 patent[s]?

THE WITNESS: As a consequence of my awareness of Shaw Kamen sequences and awareness of the presence in Bt genes, I considered that these sequences may have a destabilizing effect on Bt messenger RNA, so when I designed the example with a synthetic Btt sequence I removed ATTTA sequences.

- Q. Is this the first time that you had done a search for ATTTA sequences in the native Bt gene, as best you recall?
 - A. Referring to September 20th, 1986?
 - Q. Or thereabouts.
 - A. Yes.

A comparison of Dr. Adang's testimony regarding his laboratory notebook entries dated April of 1988, indicates that Dr. Adang had required and did acquire much more confidence and certainty than he had in 1986 that elimination of ATTTA sequences from Bt genes would solve inefficient expression problems associated with expressing the Bt genes in plants (AR 0375-0378) (emphasis added):

- Q. And can you just thumb through the pages quickly and confirm for me that for the most part the entries in this notebook appear to have been made in 1988?
- A. But I think for the most part it looks like it's for that period of 1988.
- Q. . . . Were the entries in this laboratory notebook made by employees of Agrigenetics, Inc., in the course of their employment at the company?
 - A. Yes.
- Q. Would you refer, please, to laboratory notebook page 11, which bears production number MC207642?
 - A. Yes, I see it.

- Q. There's handwriting on this page above the signatures. . . [C] an you tell me whose writing that is?
 -
 - A. Mine.
- Q. Now the last bit of text on this page states, and I quote, "The Btt sequence was scanned for sequences such as AATAAA and ATTTA that should be eliminated." Do you see that, sir?
 - A. I do.
- Q. Do you recall who did this scanning referred to here?
 - A. My recollection, it was myself.
 - Q. Why was that scanning performed?
- A. To identify where in the Btt gene and if the sequences were located in the Btt gene, where they were present.
- Q. Do you recall whether any ATTTA sequences were found?
 - A. Yes, they were.
 - Q. What did you do after you found them?
- A. After as I went through the process of redesigning the gene, I eliminated those sequences.
- Q. Can you tell me the date on which the entries on this page were made?
- A. Well, the date at the bottom right-hand corner by myself says 4-22-88. So this would have been written about that time. Sometimes I didn't sign the bottom of the page at the exact date in which I filled it in. So it would be have been written, perhaps, shortly before that date when I signed it.

Q. On or about April 12^{th} of 1988 was it your view that the ATTTA sequence should be eliminated from the native Bt gene as stated on this page?

WITNESS: Yes.

- Q. Would you turn, please, to numbered page 70 in your laboratory notebook, which bears production number MC207701?
 - A. Yes, I see that page.
- Q. Can you tell me whether your signature appears at the bottom right of that page?
 - A. Yes, it does.
 - Q. And what is the date next to your signature?
 - A. 4-25-88.
- Q. Would that signify to you that you signed this page on or about April $25^{\rm th}$, 1988?
 - A. Yes.
- Q. Can you tell me who generated the typewritten text which appears on this page?
 - A. I did.
- Q. Can you read for me the word that appears at the upper left-hand corner of this page?
 - A. "Nasties."
 - O. What are nasties in reference to?
- A. Nasties are in reference to sequences I considered potentially destabilizing of messenger RNA.

- Q. One of the sequences listed is the ATTTA sequence, about halfway down in that page; isn't that true, sir?
 - A. Yes.
- Q. As of April 25th, 1988, is it correct that you considered the ATTTA sequence to be one of the nasties because it was potentially destabilizing?

A. Yes.

- Dr. Adang's certainty in April 1988 is in marked contrast to his uncertainty that the ATTTA sequence was destabilizing messenger RNA on September 26, 1986, which we quote again (AR 0372):
 - Q. And the reason you performed the search was because you believed at the time that the ATTTA sequence was potentially a destabilizing sequence in the Bt gene that interfered with expression of the Bt gene in plants; correct?
 - A. Yes. With, you know, <u>emphasis on the term</u> "potentially," yeah. Yes.

Relative to his view of the cause of mRNA instability at the end of 1986, Dr. Adang testified (AR 0374) (emphasis added), "As a consequence of my awareness of Shaw Kamen sequences and awareness of the presence in Bt genes, I considered that these sequences may have a destabilizing effect on Bt messenger RNA"

The evidence as a whole shows that Drs. Adang and Murray identified many other potential causes for premature termination of transcription and inefficient expression of Bt genes encoding

insecticidal protein in plants. Within the period extending from December 12, 1986, through the summer of 1988, Drs. Adang and Murray performed a series of experiments, tests, computer searches, and analyzes to determine with as reasonable degree of certainty which of the suspect causes, i.e., potential solutions, was most likely to bring success. Adang has not directed our attention to any evidence of record, and we have not found any evidence of record, that indicates that before December 12, 1986, Dr. Adang or Dr. Murray had selected ATTTA as a likely cause let alone as the probable cause - of the RNA instability problem. Rather, it was merely one of many potential causes. It was only the collective gathering of evidence by Drs. Adang and Murray throughout 1987 and 1988 that enabled them to identify with confidence a cause of the problems they had experienced expressing Bt genes in plants and a way and means most likely to eliminate their problems. Compare the earlier potential solution to the later confidence with which Dr. Adama identified ATTTA as a mRNA destabilizing sequence and proposed its elimination from Bt genes in 1988:

The Btt sequence was scanned for sequences such as AATAAA and ATTTA that should be eliminated. [(AR 0376);]

Q. On or about April 12th of 1988 was it your view that the ATTTA sequence should be eliminated from the native Bt gene as stated on this page?

WITNESS: Yes. [(AR 0377); and]

Q. As of April 25th, 1988, is it correct that you considered the ATTTA sequence to be one of the nasties because it was potentially destabilizing?

A. Yes. [(AR 0378).]

We repeat the court's statement in <u>Burroughs-Wellcome Co. v.</u>

<u>Barr Labs.</u>, 40 F.3d at 1229, 32 USPQ2d at 1920:

A conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflection of the complete invention as it will be used in practice.

The kinds and amounts of experimentation and analyses Adang performed, and the related testimony of Adang's inventors and associates, indicate that prior to December 12, 1986, Adang did not have "'a definite and permanent idea of the complete and operative invention [of Count 2], as it is therefore to be applied in practice.' Coleman v. Dines, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985) . . ", Kridl v. McCormick, 105 F.3d 1446, 1449, 41 USPQ2d 1686, 1689 (Fed. Cir. 1997), or so clearly defined the invention of Count 2 that "only ordinary skill would have been necessary to reduce the invention to practice, without extensive research or experimentation,"

Burroughs-Wellcome Co. v. Barr Labs., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). Nevertheless, even assuming

that the evidence of record as a whole is sufficient to establish Adang's conception of the invention of Count 2 prior to December 12, 1986, for reasons stated hereinabove, we are not satisfied that Adang exercised reasonable diligence toward reduction to practice of an invention of any claim defining Count 2, from just prior to Fischhoff's December 12, 1986, conception of the invention of Count 2, to Adang's September 9, 1988, constructive reduction to practice. Senior Party Adang has not shown that it was first to invent the subject matter of Count 2 of this interference.

5. Adang's Argument: VI. The Unpatentability of Fischhoff's Claims In View of the Invention of Kenneth Barton and Michael Miller

A. Adang's complaint

Adang complains that an APJ abused its discretion in two ways. First, the APJ is said to have abused its discretion by denying Adang permission to renew its previously filed Preliminary Motion No. 3 under 37 CFR § 1.633(a) and request for discovery (Paper No. 47) or to file a new preliminary motion under 37 CFR § 1.633(a) and new request for discovery. Second, the APJ is said to have abused its discretion by refusing to remand Fischhoff's involved application to a primary examiner for judgment on the patentability of all Fischhoff's claims designated as corresponding to the interference count under

35 U.S.C. § 102(g) or § 103 in view of the "possible" prior invention thereof by Barton.

B. Abuse of discretion standard

Interlocutory orders regarding procedural matters are reviewed at final hearing for abuse of discretion. 37 CFR 1.655(a). The burden of showing that an interlocutory order should be modified is on the party attacking the order. 37 CFR 1.655(a). "An abuse of discretion occurs if the decision (1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision." Abrutyn v. Giovanniello, 15 F.3d 1048, 1050-51, 29 USPQ2d 1615, 1617 (Fed. Cir. 1994).

It is not an abuse of discretion for the Board to decline consideration of arguments which are untimely presented. <u>Credle v. Bond</u>, 25 F.3d 1566, 1572 n.14, 30 USPQ2d 1911, 1916 n.14 (Fed. Cir. 1994).

C. Summary of the facts

Following the instructions of the Federal Circuit, the interference was redeclared, naming Barton as a junior inventor, in order to finalize the count before Monsanto elected Barton or Fischhoff as the earliest inventor of the invention defined by

the interference count. When the interference was redeclared, the APJ ordered the parties to the interference to specify what preliminary motions needed to be filed and explain why. Adang, which had recently retained new counsel, did not renew its previously filed request for judgment as to the patentability of Fischhoff's claims corresponding to the count under 35 U.S.C. \$ 102(g)/103 in view of Junior Party Barton's invention or discovery. In due course, Monsanto elected Fischhoff as first to invent the subject matter of the count. Thereafter, Adang sought leave to renew its previously filed request for judgment and discovery, to file a new request for judgment and discovery, or to remand to the primary examiner. The APJ denied Adang's new request. Consideration of the complete record, as opposed to Adang's abbreviated summary, yields no evidence supporting Adang's story of abuse of discretion.

D. Background

November 7, 1996 - Interference 103,781 was initially declared essentially as follows (Paper No. 2):

JUNIOR PARTY APPLICATION

Named Inventors: Kenneth A. Barton and Michael J. Miller

Application: Application 07/827,906, filed

January 30, 1992

Title: Improved Expression of Genes in Plants

Assignee: None (assignment to Monsanto Company

recorded October 15, 1996; assignment to Monsanto Technology LLC recorded

June 13, 2001)

Accorded benefit for the purpose of

priority of:

Application 07/390,561, filed August 7,

1989

JUNIOR PARTY APPLICATION

Named Inventors: David A. Fischhoff and Frederick J.

Perlak

Application: Application 08/434,105, filed May 3,

1995

Title: Synthetic Plant Genes and Method for

Preparation

Assignee: None (assignment to Monsanto Technology

LLC recorded June 13, 2001)

Accorded benefit for the purpose of

priority of:

Application 07/959,506, filed October 9, 1992, now U.S. Patent 5,500,365, issued March 3, 1996; Application 07/476,661, filed February 12, 1990, now abandoned;

and Application 07/315,355, filed February 24, 1989, now abandoned

SENIOR PARTY PATENT

Named Inventors: Michael J. Adang, Thomas A. Rocheleau,

Donald J. Merlo and Elizabeth E. Murray

Application: Application 08/057,191, filed May 3,

1993, now U.S. Patent 5,380,831, issued

January 10, 1995

Title: Synthetic Insecticidal Crystal Protein

Gene

Assignee:

Mycogen Plant Science, Inc. (Paper

No. 13)

Accorded benefit for the purpose of priority of:

Applications 07/827,844, filed January 28, 1992, now abandoned, and Application 07/242,482, filed September 9, 1988, now abandoned

Count 1

A method of designing a synthetic <u>Bacillus</u> thuringiensis gene to be more highly expressed in plants, comprising the steps of:

- a) analyzing the coding sequence of a gene derived from <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence, or
- b) analyzing the coding sequence of a gene derived from <u>Bacillus thuringiensis</u> which encodes an insecticidal protein toxin, and modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence and fewer plant polyadenylation signals than said coding sequence.

The claims of the parties which were designated to correspond to this count were:

Barton et al.: Claims 1-4, 7, and 15-22

Fischhoff et al.: Claims 3, 5, and 39-43

Adang et al.: Claims 1-14.

December 12, 1996 - An APJ entered an Order to Show Cause stating (Paper No. 11, pp. 1-2, bridging para.):

In view of the common ownership by Monsanto Company of the Barton application and the Fischhoff application, the junior party Barton is ordered to show cause why judgment should not be entered against him within 30 days from the date of this order. Monsanto Company, as the assignee of both Barton and Fischhoff, may name the prior inventor in response to this order. Cf. M.P.E.P. 2302.

January 17, 1997 - The APJ ordered Monsanto Company "to name the prior inventor of count 1 . . . In the event Monsanto makes no election, judgment will be entered against junior party Barton" (Paper No. 29, p. 3).

February 3, 1997 - Barton petitioned the Commissioner under 37 CFR § 1.644(a)(1) to reverse or postpone the APJ's January 17, 1997 order (Paper No. 35).

March 26, 1997 - Barton's February 3, 1997, petition was denied (Paper No. 38).

May 8, 1997 - Adang filed Adang et al.'s Contingent
Preliminary Motion 3 (Paper No. 47) whereby Adang moved for
judgment that Claims 3, 5, 39, 40 and 41-43 of Fischhoff's
involved application are unpatentable under 35 U.S.C. § 102(g) or
§ 103 over a prior invention of Barton et al. "if deposition and
documentary discovery [requested] should show that the claims are
not patentable to Fischhoff et al. in view of the possible prior
invention of Barton et al." (Paper No. 47, para. bridging pp. 1
& 2). According to Adang (Paper No. 47, p. 1, para. 1):

This is a contingent Motion, that should only be considered if the APJ believes that, notwithstanding Monsanto's election of Fischhoff et al. over Barton et al., Barton et al., is still available to the parties as 102(g)/103 prior art.

June 19, 1997 - The Board entered the following judgment (Paper No. 53):

Whereas Monsanto, the common assignee of the Barton et al. and Fischhoff et al. applications has named the party Fischhoff et al. as the prior inventor of count 1, pursuant to 37 CFR 1.602(a) and 1.610(e) judgment is hereby entered against Barton et al. as to the subject matter of count 1. Accordingly, Kenneth A. Barton and Michael J. Miller are not entitled to a patent containing Claims 1-4, 7, and 15-22 corresponding to count 1. The interference will continue as Fischhoff et al. v. Adang et al.

June 27, 1997 - Barton filed notice under 35 U.S.C. §§ 141 and 142 of appeal to the U.S. Court of Appeals for the Federal Circuit from the judgment of the Board entered June 17, 1997 (Paper No. 55).

February 5, 1998 - The U.S. District Court for the District of Delaware entered a judgment (Mycogen Plant Science, Inc. v. Monsanto Co., No. 96-505 (D. Del. Feb. 5, 1998)) in an action brought by Mycogen Plant Science, Inc., and Agrigenetics Inc. against Monsanto Co., DeKalb Genetics Corp., and Delta and Pine Land Co. for infringement of two Mycogen patents (Adang et al., U.S. Patent 5,567,862, entitled "Synthetic Insecticidal Crystal Protein Gene," issued October 22, 1996, from U.S. Application 08/369,839, filed January 6, 1995; and Adang et al., U.S. Patent

5,567,600, entitled "Synthetic Insecticidal Crystal Protein Gene," issued October 22, 1996, from U.S. Application 08/369,835, filed January 6, 1995). A jury rendered a verdict that

(1) defendants' products did not literally infringe any of the contested claims of Mycogen's patents, and (2) all of the contested claims of Mycogen's patents are invalid because Monsanto invented the subject matter thereof before the priority dates of Mycogen's patents. See the Procedural History in Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1320-1321, 58 USPQ2d 1030, 1033-1034 (Fed. Cir. 2001) (Paper No. 125).

December 9, 1998 - The Court of Appeals for the Federal Circuit reversed the Board's June 19, 1997, judgment and remanded (Paper No. 124). Barton v. Adang, 162 F.3d 1140, 1146, 49 USPQ2d 1128, 1134 (Fed. Cir. 1998) (Paper No. 118, Exhibit A). The court instructed "the Board to continue the three-party interference until the Board determines the final count and discovery is complete." Barton v. Adang, 162 F.3d at 1146, 49 USPQ2d at 1134.

September 8, 1999 - The U.S. District Court for the District of Delaware entered a revised order (Paper No. 125, Exh. H) and ruling on post-trial motions (Paper No. 125, Exh. I) (Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F.2d 199 (D. Del. 1999)).

See Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1321, 58 USPQ2d at 1034 (Paper No. 146):

The district court granted Monsanto's motion for JMOL holding that the claims of the '600 and '862 patents were invalid for lack of enablement pursuant to 35 U.S.C. § 112.

September 8, 1999 - The U.S. District Court for the District of Delaware entered a final judgment (Monsanto Co. v. Mycogen

Plant Science, Inc., No. 96-133-RMN (D. Del. Sept. 8, 1999)) in an action brought by Monsanto Co. against Mycogen for infringement of Claims 7-9 and 12 of Monsanto's U.S. Patent 5,500,365 (Fischhoff et al., U.S. 5,500,365, issued Mar. 19, 1996, assigned to Monsanto Company). Monsanto Co. v. Mycogen

Plant Science, Inc., 261 F.3d 1356, 1359-61, 59 USPQ2d 1930, 1931-32 (Fed. Cir. 2001).

November 10, 1999 - In an action brought by Mycogen Plant Science, Inc. and Agrigenetics Inc. against Monsanto Company for infringement of plaintiff's patent (Adang et al., U.S. Patent 5,380,831, issued January 10, 1995, from U.S. Application 08/057,191, filed May 3, 1993), the U.S. District Court for the Southern District of California entered an order (Mycogen Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal. Nov. 10, 1999) (Paper No. 127, Exh. A) granting defendant's motion for summary judgment that Claims 1-12 of Mycogen's '831 patent are invalid under 35 U.S.C. § 102(g) and/or § 103 because Monsanto invented the subject matter thereof before Mycogen, as determined by the U.S. District Court for the District of Delaware in

Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F.Supp.2d 199

(D. Del. 1999), affirmed in Mycogen Plant Sci., Inc. v. Monsanto

Inc., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001), and denied defendant's motion for summary judgment that the contested claims of Mycogen's '831 patent are invalid for noncompliance with the enablement requirement of the first paragraph of 35 U.S.C. § 112 as moot (Paper No. 127, Exh. A).

March 12, 2001 - On appeal from the decision of the U.S. District Court for the District of Delaware in Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F.Supp.2d 199 (D. Del. 1999), the U.S. Court of Appeals for the Federal Circuit:

. . . affirm[ed] the verdict of noninfringement based on patent invalidity due to prior invention pursuant to 35 U.S.C. § 102(g). This makes it unnecessary to address the finding of lack of enablement pursuant to 35 U.S.C. § 112.

Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d at 1320,
58 USPQ2d at 1033 (Paper No. 146).

May 30, 2001 - On appeal from the decision of the U.S.

District Court for the Southern District of California in Mycogen

Plant Sci., Inc. v. Monsanto Co., No. 95-CV-653 (S.D. Cal.

Nov. 10, 1999) (Paper No. 127, Exh. A), the U.S. Court of Appeals

for the Federal Circuit affirmed-in-part, reversed-in-part, and

remanded. Mycogen Plant Sci., Inc. v. Monsanto Co., 252 F.3d

1306, 1309-1310, 58 USPQ2d 1891, 1892-1893 (Fed. Cir. 2001).
The Federal Circuit concluded at 1309, 58 USPQ2d at 1893, that:

. . . the district court improperly resolved disputed questions of material fact pertaining to the issue of prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding.

Id. at 1310, 58 USPQ2d at 1894, the Federal Circuit explained:

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention [claimed in the Mycogen's '831 patent] to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen was the first to conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

August 16, 2001 - On appeal from the decision of the U.S.

District Court for the District of Delaware in Monsanto Co. v.

Mycogen Plant Science, Inc., No. 96-133-RMN (D. Del. Sept. 8,
1999), the U.S. Court of Appeals for the Federal Circuit

affirmed. Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d
1356, 1359, 59 USPQ2d 1930, 1931 (Fed. Cir. 2001). At 1360,
59 USPQ2d at 1932, the Federal Circuit said, "Claims 7-9 and 12

are at issue" Claims 7-9 and 12 of Fischhoff's U.S.

Patent 5,500,365 are drawn to modified chimeric genes, and plants transformed by modified chimeric genes, comprising a structural coding sequence modified to contain "at least one fewer sequence selected from the group consisting of a AACCAA and an AATTAA sequence." Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d at 1360-61, 59 USPQ2d at 1932. Claims 4-6 and 11 of the same patent, which were not at issue, are directed to modified chimeric genes, and plants transformed by modified chimeric genes, comprising a structural coding sequence modified to contain "at least one fewer sequence selected from the group consisting of plant polyadenylation sequences and an ATTTA sequence." Columns 45-47 of Fischhoff et al, U.S. Patent 5,500,365.

January 8, 2002 - Adang appointed new counsel (Paper No. 147).

September 4, 2002 - An APJ entered a Decision and Order On Preliminary and Miscellaneous Motions and Requests (Paper No. 148), which, <u>inter alia</u>:

denied Adang's Contingent Preliminary Motion 3 (Paper No. 47) under 37 CFR § 1.633(a) for judgment that Claims 3, 5, and 39-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, designated as corresponding to the

interference count, are unpatentable under 35 U.S.C. § 102(g) over at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count, or under 35 U.S.C. § 103 in view of prior art including the subject matter of at least one claim of Barton's U.S. Application 07/827,906, filed January 30, 1992, designated as corresponding to the count;

denied Adang's contingent request (Paper No. 47) for permission to seek deposition and documentary discovery relevant to Monsanto's presumed determination and/or election, as between Fischhoff and Barton, of Barton as first to invent the subject matter defined by the count;

ordered Interference 103,781 "redeclared as <u>Barton</u> (U.S. Application 07/827,906) or Fischhoff (U.S. Application 08/434,105) v. Adang (U.S. Patent 5,380,831)" (Paper No. 148) with the following new Count 2:

Count 2

Any one of Claims 1-4, 7, and 15-22 of Barton et al.'s Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 3, 5, and 39-43 of Fischhoff et al.'s Application 08/434,105, filed May 3, 1995;

- or -

Any one of Claims 1-14 of Adang et al.'s
U.S. Patent 5,380,831, which issued January 10, 1995,
from U.S. Application 08/057,191, filed May 3, 1993.

Barton's Claims 1-4, 7, and 15-22; Fischhoff's Claims 3, 5, and 39-43; and Adang's Claims 1-14; were designated as corresponding to new Count 2;

ordered the parties to specify whether the time for filing preliminary motions should be extended;

ordered the parties to specify what additional preliminary motions, if any, and supporting evidence, if any, need be filed in this newly declared interference; and

ordered the parties to explain why the additional preliminary motions and supporting evidence specified are necessary to, and should be filed in, this interference proceeding.

November 26, 2002 - Adang filed a REQUEST FOR RECONSIDERATION and RESPONSES RE: THE DECISION ON MOTIONS AND REQUEST (Paper No. 154):

I. alternatively asking the Board to:

require Monsanto to elect the first to invent the subject matter defined by Count 2 as between Barton and Fischhoff;

remand the Barton and Fischhoff applications to a primary examiner to require identification of Fischhoff or Barton as the

first to invent the subject matter defined by Count 2 under 37 CFR § 1.78(c); or

declare separate interferences, <u>i.e.</u>, Fischhoff v. Adang and Barton v. Adang;

II. asking the Board for leave to file preliminary motions under 37 CFR \$ 1.633(a) for judgment that:

Barton is not entitled to a patent containing Barton's claims designated as corresponding to Count 2 in view of Monsanto's alleged violation of 37 CFR § 1.56; and

Fischhoff is not entitled to a patent containing Fischhoff's claims designated as corresponding to Count 2 in view of Monsanto's alleged violation of 37 CFR § 1.56;

III. asking the Board for leave to file a miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR § 1.687(c) relating to Monsanto's alleged violation of 37 CFR § 1.56;

IV. asking the Board for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Barton's Claims 21 and 22 are unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement);

V. asking the Board for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Fischhoff's

Claim 40 is unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement);

VI. asking the Board for leave to file a preliminary motion under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by excluding Adang's Claims 2, 3, 5-7, 9, 10, 13 and 14 from Count 2;

VII. asking the Board for leave to file a renewed or amended miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR § 1.687© relating to derivation of invention; and

VIII. asking the Board to refrain from adding Mycogen's U.S. Patents 6,013,523 and 6,015,891 to this interference.³

December 9, 2002 - Fischhoff and Barton filed Joint Comments
Concerning Adang's Request for Reconsideration and Responses Re:
the Decision on Motions and Requests (Paper No. 161) asking the
Board to dismiss Adang's request for reconsideration; deny
Adang's requests for leave to file every new preliminary motion

Note that Adang's REQUEST FOR RECONSIDERATION and RESPONSES RE: THE DECISION ON MOTIONS AND REQUEST, filed November 26, 2002 (Paper No. 154), did not request permission to file a new or renewed motion under 37 CFR § 1.633(a) for judgment that Fischhoff's claims designated as corresponding to the count are unpatentable under 35 U.S.C. § 102(g)/103 over a prior invention of Barton et al. or request or renew it previous request for discovery of any information which might support the new or renewed motion.

it proposes to file but for Adang's request for leave to file a motion under 37 CFR § 1.633(a) to declare Barton's Claims 21 and 22 unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement); and set a time period for Barton to file its preliminary statement.

May 20, 2003 - An APJ entered a DECISION AND ORDER ON PROPOSED PRELIMINARY AND MISCELLANEOUS MOTIONS AND REQUESTS (Paper No. 164):

denying Adang's request to require Monsanto to designate Fischhoff or Barton as first to invent the subject matter of Count 2 (Paper No. 154);

denying Adang's requests for leave to file preliminary motions under 37 CFR § 1.633(a) for judgment that all Fischhoff and Barton claims designated as corresponding to Count 2 are unpatentable due to common assignee Monsanto's purported violations of 37 CFR § 1.56 (Paper No. 154);

denying Adang's request for leave to file a miscellaneous motion under 37 CFR § 1.635 for additional discovery under 37 CFR § 1.687(c) relating to Monsanto's purported violation of 37 CFR § 1.56 (Paper No. 154);

granting Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Claims 21 and 22 of Barton's Application 07/827,906, filed January 30, 1992, are

unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement) (Paper No. 154);

denying Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(a) for judgment that Claim 40 of Fischhoff's Application 08/827,906, filed May 3, 1995, is unpatentable under 35 U.S.C. § 112, first paragraph (written description requirement) (Paper No. 154);

denying Adang's request for leave to file a preliminary motion under 37 CFR § 1.633(c)(1) to redefine the interfering subject matter by excluding Claims 2, 3, 5-7, 9, 10, 13 and 14 of Adang's U.S. Patent 5,380,831 from this interference (Paper No. 154); and

denying Adang's request for leave to renew or amend a motion under 37 CFR § 1.635 said to have been filed earlier "for discovery under 37 CFR § 1.687(c) Re: Derivation of Invention" (Paper No. 154).

June 3, 2003 - Adang filed a Request For Reconsideration (Paper No. 166) of the APJ's Decision And Order On Proposed Preliminary And Miscellaneous Motions And Requests, dated May 20, 2003 (Paper No. 164).

June 5, 2003 - An APJ entered a Decision On Adang's Request For Reconsideration (Paper No. 168), granting-in-part and

denying-in-part Adang's Request For Reconsideration (Paper No. 166).

July 18, 2003 - Fischhoff filed Monsanto Election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, vis-a-vis the Junior Party Barton et al., the subject matter defined by Count 2" and statement of intent not to submit "any further documents in this interference on behalf of the Junior Party Barton" (Paper No. 182).

July 21, 2003 - Adang filed a Request For Immediate Entry Of Judgment Against Barton (Paper No. 198).

July 22, 2003 - Adang filed a Request For Authorization
To Address The Unpatentability Of Fischhoff's Claims [under
35 U.S.C. § 102(g) in view of Barton's invention of subject
matter within the scope of Count 2] And To Obtain Related
Discovery (Paper No. 199).

July 28, 2003 - Adang filed Adang's Supplemental Preliminary Statement (Paper No. 208).

July 29, 2003 - An APJ entered a Decision On Adang's Requests For Immediate Entry Of Judgment Against Barton And Authorization To Address The Unpatentability Of Fischhoff's Claims And To Obtain Related Discovery (Paper No. 212) denying Adang's July 21, 2003, and July 22, 2003, requests.

August 8, 2003 - Adang filed Adang's Notice Under 37 CFR § 1.640(b) for review of the following at final hearing (Paper No. 219):

- 1. Issues relating to priority of invention between the parties to this interference;
- September 4, 2002, Order and Decision on Motions (Paper No. 148);
- 3. May 20, 2003, Order and Decision on Motions;
- 4. June 18, 2003, Decision on Adang's Request for Reconsideration;
- 5. July 29, 2003, Decision on Adang's Requests for Immediate Entry Of Judgment Against Barton and For Authorization to Address the Unpatentability of Fischhoff's Claims and to Obtain Related Discovery (Paper No. 212); and
- 6. Any decisions or matters raised <u>sua sponte</u> with respect to Adang's Case-in-Rebuttal which are entered after the filing of this notice.

E. Facts

The record shows that, after redeclaring the interference with Barton again designated as a junior party to the interference in accordance with the Federal Circuit's decision, the APJ ordered Adang to specify what preliminary motions need be filed and explain why they were necessary (Paper No. 148). Although accorded the opportunity to respond, Adang did not indicate, or explain why, a new or renewed preliminary motion under 37 CFR § 1.633(a) for judgment under 35 U.S.C. § 102(g)/103 in view of the "possible" prior invention thereof by Barton and request for discovery was necessary (Paper No. 154). Adang had

recently retained the services, and thereafter followed the advice, of new counsel (Paper No. 147).

Monsanto subsequently filed an election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, vis-a-vis the Junior Party Barton et al., the subject matter defined by Count 2" (Paper No. 182). In the same paper, Monsanto stated its intent not to submit "any further documents in this interference on behalf of the Junior Party Barton" (Paper No. 182). Adang thereafter belatedly asked for permission to: renew its previously filed preliminary motion under 37 CFR § 1.633(a) and request for discovery (Paper No. 47); file a new preliminary motion under 37 CFR § 1.633(a) and request for discovery; or remand Fischhoff's involved application to a primary examiner for judgment on the patentability of all Fischhoff's claims designated as corresponding to the interference count under 35 U.S.C. § 102(g)/103 in view of the "possible" prior invention thereof by Barton (Paper No. 199). The APJ denied Adang's new request because: (1) the request had not been timely filed; and (2) the request did not adequately explain the basis for the motion and request for discovery (Paper No. 212). The record does not support Adang's story of abuse of discretion.

Hoping to discover any evidence indicating that Fischhoff's claims designated as corresponding to the count are unpatentable in view of a "possible prior invention by Barton," Adang moved on May 8, 1997, for judgment that all of Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 over whatever evidence may possibly be discovered indicating the prior invention thereof by Barton (Paper No. 47). At the time Adang filed its motion, an APJ had already ordered Monsanto to name the prior inventor of the interference count as between commonly assigned Barton and Fischhoff (Paper No. 29), Monsanto had elected Fischhoff as first to invent the interfering subject matter, Barton had petitioned the Commissioner to reverse or postpone the APJ's order (Paper No. 35), and Barton's petition had been denied (Paper No. 38).

The Board entered judgment against Barton relative to the invention defined by the then existing count (Paper No. 53), Barton appealed the judgment to the Federal Circuit (Paper No. 55), and the Federal Circuit reversed and remanded instructing the Board that its requirement for Monsanto to elect the first to invent the subject matter of the interference count as between Barton and Fischhoff had been premature before the scope of the count was final and discovery was complete.

Barton v. Adang, 162 F.3d 1140, 1146, 49 USPQ2d 1128, 1134 (Fed.
Cir. 1998) (Paper No. 118, Exhibit A).

Subsequently, the Federal Circuit entered in quick succession three decisions on appeal of judgments of the U.S. district courts of Delaware (2) and Southern California in actions for infringement of three Adang patents (U.S. Patents 5,567,862 and 5,567,600 (Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001) (Delaware I); and involved 5,380,831 (Mycogen Plant Sci., Inc. v. Monsanto, Inc., 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001) (Delaware II)); and one Fischhoff patent (U.S. Patent 5,500,365 (Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d 1356, 59 USPQ2d 1930 (Fed. Cir. 2001) (Delaware II); all appeals involving Barton, Fischhoff and Adang and/or their assignees. Only in Delaware II had Barton been determined to be first to invent subject matter also claimed by Fischhoff. However, the subject matter at issue in Delaware II was narrowly defined by Claims 7-9 and 12 of Fischhoff's U.S. Patent 5,500,365 and did not include Claims 4-6 and 11 of the same patent. Claims 7-9 and 12 of Fischhoff's patent are drawn to modified chimeric genes, and plants transformed by modified chimeric genes, comprising a structural coding sequence modified to contain "at least one fewer sequence selected from the group consisting of an AACCAA

and an AATTAA sequence." Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d at 1360-61, 59 USPQ2d at 1932. Claims 4-6 and 11 of same patent, the subject matter of which was not at issue in the case, are directed to modified chimeric genes, and plants transformed by modified chimeric genes, comprising a structural coding sequence modified to contain "at least one fewer sequence selected from the group consisting of plant polyadenylation sequences and an ATTTA sequence" (Fischhoff's U.S. Patent 5,500,365, cols. 45-47).

During the preliminary motion phase of this interference proceeding without Barton, Adang had filed Preliminary Motion No. 3 (Paper No. 47) on May 8, 1997, for judgment on the patentability of Fischhoff's claims designated as corresponding to the existing count under 35 U.S.C. § 102(g)/103 and discovery for possible evidence that Barton was first to invent the subject matter defined by Fischhoff's claims corresponding to the count. Adang appointed new counsel on January 8, 2002 (Paper No. 147).

Adang's Preliminary Motion No. 3 was denied as premature (Paper No. 148, mailed September 4, 2002). Also redeclaring the interference to reinstate Barton as a junior party, the APJ ordered the parties to specify what additional preliminary motions were required and explain why they were necessary (Paper No. 148). In response, Adang did not ask to file or refile a

preliminary motion for judgment as to the patentability of Fischhoff's claims designated as corresponding to the existing count under 35 U.S.C. § 102(g)/103 in view of Barton's prior invention or request discovery for possible evidence that Barton was first to invent the subject matter defined by Fischhoff's claims corresponding to new Count 2 (Paper No. 154). Nor did Adang explain why a new or renewed preliminary motion under 37 CFR § 1.633(a) for judgment under 35 U.S.C. § 102(g)/§ 103 in view of the "possible" prior invention thereof by Barton and the request for discovery were necessary (Paper No. 154).

On its own volition, Monsanto filed an election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, vis-a-vis the Junior Party Barton et al., the subject matter defined by Count 2" and a statement of intent not to submit "any further documents in this interference on behalf of the Junior Party Barton" (Paper No. 182, filed July 21, 2003).

Thereafter, Adang requested permission to file a preliminary motion under 37 CFR § 1.633(a) and request discovery, or remand Fischhoff's involved application to a primary examiner for judgment of the patentability of all Fischhoff's claims designated as corresponding to the interference count under 35 U.S.C. § 102(g)/103 in view of the possible prior invention thereof by Barton. The request was filed after the time period

set for such a request in the Decision and Order On Preliminary and Miscellaneous Motions and Requests, mailed September 4, 2002 (Paper No. 148) had lapsed (Paper No. 199). The APJ explained the denial of Adang's new request as follows (Paper. No. 212, pp. 10-11):

Finally, the decision to which Adang refers was published 2001 (. . . [Paper No.] 199, p. 5). The Board granted Adang ample opportunity to specify and explain why the discovery it now seeks is necessary to this interference in the Decision and Order On Preliminary and Miscellaneous Motions and Requests, mailed September 4, 2002 (Paper No. 148). Adang allowed that window of opportunity [to] close.

Now, Adang's belated request amounts to a motion under 37 CFR § 1.635 to consider a new request to file yet another preliminary motion under 37 CFR § 1.633(a) for judgment that Fischhoff's claims corresponding to the count are unpatentable under 35 U.S.C. § 102(g) over nonelected Junior Party Barton's claims. 37 CFR § 1.645(b) reads:

Any paper belatedly filed will not be considered except upon motion (§ 1.635) which shows good cause why the paper was not timely filed. . . .

Adang has not shown good cause why its belated request was not timely filed. Accordingly, Adang's new request is denied.

F. Discussion

Senior Party Adang's Brief At Final Hearing (Paper No. 223, pp. 60-64) tells a story of Adang's "Catch-22" efforts to file preliminary motions for discovery and judgment that Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 in view of the

"possible" prior invention thereof by Barton. According to Adang, its first attempt to file the motion (Paper No 47) was denied as premature pending Barton's reinstatement as a junior party to this interference, motions necessitated thereby, and finalization of the scope of the count. Adamg has not suggested that the APJ erred in denying its initial motion, i.e., Preliminary Motion No. 3 (Paper No. 47), for the reasons given in the APJ's decision thereon (Paper No. 148). According to Adang's story, however, a "Catch-22" situation, and concomitant abuse of discretion by the APJ, arose because the APJ subsequently denied (Paper No. 212) Adang's request to refile the motion (Paper No. 199). The request was denied for, inter alia, untimeliness (Paper No. 212) following Barton reinstatement as junior party to the interference (Paper No. 148) and Monsanto's election thereafter of Fischhoff as first to invent the subject matter of the interference count as between Barton and Fischhoff (Paper No. 182). In its brief at final hearing, Adang asks the Board to consider how an APJ can have fairly denied its first motion (Paper No. 47) as premature without Barton (Paper No. 148), and then fairly denied Adang's request to file a second motion or renew its earlier motion (Paper No. 199) after Barton's reinstatement (Paper No. 148) because the request was untimely (Paper No. 212).

The short answer is that Adang was accorded the opportunity to file a request to file a motion for judgment and additional discovery, but it failed to do so. In its belated request to file a motion for judgment under 35 U.S.C. § 102(g)/103 in view of Barton's invention and discovery, Adang failed to show good cause for its initial failure to file a timely request. It was not an abuse of discretion to deny the belated request. Credle v. Bond, 25 F.3d at 1572 n.14, 30 USPQ2d at 1916 n.14.

That the APJ did not abuse its discretion is apparent from the record. Following the redeclaration of the interference, with Barton reinstated as a junior party (Paper No. 148), the APJ ordered all parties to the interference, and set reasonable time periods for all the parties, to (1) specify what additional preliminary motions were required as a result of the interference being redeclared with Barton as a junior party, and (2) explain why those motions were necessary (Paper No. 148). In responding to that order, and in its subsequent request for reconsideration of decisions relating to that order, Adang did not specify any motion under 37 CFR § 1.633(a) for discovery and judgment that Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 in view of the possible prior invention thereof by Barton. Nor did Adang explain why a motion under 37 CFR § 1.633(a) for

discovery and judgment that Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 in view of the possible prior invention thereof by Barton was, or might be, necessary (Adang's REQUEST FOR RECONSIDERATION and RESPONSES RE: THE DECISION ON MOTIONS AND REQUEST (Paper No. 154); APJ's DECISION AND ORDER ON PROPOSED PRELIMINARY AND MISCELLANEOUS MOTIONS AND REQUESTS (Paper No. 164); Adang's Request For Reconsideration (Paper No. 166) of the APJ's Decision And Order On Proposed Preliminary And Miscellaneous Motions And Requests; and APJ's Decision (Paper No. 168) on Adang's Request For Reconsideration, granting-in-part and denying-in-part Adang's Request For Reconsideration).

Before Adang finished timely responding and requesting reconsideration of responses to the APJ's order to specify and explain what motions were necessary as a result of the redeclaration of the interference with Barton reinstated as a junior party, Adang knew that the interference had been redeclared with Barton reinstated as a junior party; Adang knew that the interference had been redeclared with new Count 2 being alternatively directed to each claim pending in Barton's involved application, each claim pending in Fischhoff's involved application, and every claim of Adang's involved patent; Adang knew that the Federal Circuit had decided Barton v. Adang,

162 F.3d 1140, 49 USPQ2d 1128 (Fed. Cir. 1998); Mycogen Plant
Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed.
Cir. 2001) (Delaware I); Mycogen Plant Sci., Inc. v. Monsanto,
Inc., 252 F.3d 1306, 58 USPQ2d 1891 (Fed. Cir. 2001); and
Monsanto Co. v. Mycogen Plant Science, Inc., 261 F.3d 1356,
59 USPQ2d 1930 (Fed. Cir. 2001) (Delaware II); and Adang knew
that Claims 7-9 and 12 of Fischhoff's noninvolved U.S. Patent
5,500,365, were the only claims at issue in Delaware II and were
limited to modified chimeric genes comprising a structural coding
sequence modified to contain "at least one fewer sequence
selected from the group consisting of an AACCAA and an AATTAA
sequence." Adang was also on notice that the subject matter
defined by new Count 2 of this interference was far broader in
scope than the subject matter encompassed by Claims 7-9 and 12 of
Fischhoff's U.S. Patent 5,500,365.

After Fischhoff filed Monsanto Election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, vis-a-vis the Junior Party Barton et al., the subject matter defined by Count 2" and the statement of intent not to submit "any further documents in this interference on behalf of the Junior Party Barton" (Paper No. 182) on July 18, 2003, Adang then filed its Request For Authorization To Address The Unpatentability Of Fischhoff's Claims [under 35 U.S.C. § 102(g)

in view of Barton's prior invention of subject matter within the scope of Count 2] And To Obtain Related Discovery (Paper No. 199). Adang's Request For Authorization To Address The Unpatentability Of Fischhoff's Claims [under 35 U.S.C. § 102(g) in view of Barton's invention of subject matter within the scope of Count 2] And To Obtain Related Discovery (Paper No. 199) was not filed in the time period set in the Decision and Order On Preliminary and Miscellaneous Motions and Requests (Paper No. 148) and was properly denied for that reason alone (Paper No. 212). Nevertheless, justice demands consideration whether Adang's belated request then should have been and/or now should be excused for good cause (37 CFR § 1.645(b)). Looking for such good cause, we turn to Adang's brief at final hearing.

Initially, we find Adang's "Catch-22" argument to be a fact-deficient presentation of the events leading to the denial of Adang Request For Authorization To Address The Unpatentability Of Fischhoff's Claims under 35 U.S.C. § 102(g) in view of Barton's invention of subject matter within the scope of Count 2 And To Obtain Related Discovery (Paper No. 199). Adang failed to mention that the APJ had set a time period for the parties to request permission to file additional preliminary motions and explain why the additional motions requested were necessitated by redeclaration of the interference with new Count 2 and Barton as

a junior party (Paper No. 148). Adang's shorthand version of the events of record defies excuse.

Secondly, the APJ had ordered Adang to indicate what motions, for example a renewed motion under 37 CFR § 1.633(a) for discovery and judgment that Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 in view of the possible prior invention thereof by Barton, were required and to explain why they were necessary. Apparently, Adang belatedly came to think that it had not adequately responded to the APJ's order within the time period set. However, Adang has never adequately explained why it failed to do so. This failure is yet another basis to deny the request, for no "good cause" has been shown to excuse the lapse.

Adang's Brief at Final Hearing suggests that a motion under 37 CFR § 1.633(a) for discovery and judgment that Fischhoff's claims designated as corresponding to the interference count are unpatentable under 35 U.S.C. § 102(g)/103 in view of the possible prior invention thereof by Barton was not required before

Monsanto elected Fischhoff as first to invent the subject matter of Count 2 as between Barton and Fischhoff. According to Adang, the new or renewed motion and request were not appropriate before Monsanto elected Fischhoff as first to invent the subject matter

of Count 2 as between Barton and Fischhoff. Adang has not explained the why of it.

In its brief, Adang states (AB 62, second full para.):

The APJ rejected Adang's motion [(Paper No. 199)].
... [T]he APJ denied Adang's request for leave to file a belated preliminary motion, stating that Monsanto's election does not warrant untimely reconsideration of the Board's earlier denial of Adang's Contingent Preliminary Motion 3. (Paper No. 212, pages 4-5 & 11). The APJ also stated that such issues could have been timely raised at the time the interference was redeclared [(Paper No. 148)] adding Barton into the interference (Paper No. 212, pages 6-11.)

Adang then argues that it was reasonable for Adang to presume that (AB 62-63, bridging para.):

. . . reconsideration [requested] any time before Monsanto had made its election . . . would clearly have been premature under the APJ's rationale set forth in the Order redeclaring the interference (Paper No. 148, pages 30-32). Having requested reconsideration immediately after the election was filed cannot properly be deemed belated.

However, at the time Monsanto made its election, Barton had been reinstated as a junior party to the interference. At the time Monsanto made its election, the scope of Count 2 had been set in the Decision and Order On Preliminary and Miscellaneous Motions and Requests (Paper No. 148). At the time Monsanto made its election, the Federal Circuit had decided the pending appeals of the decisions in the Delaware I, Delaware II, and California infringement proceedings. At the time Monsanto made its election, Adang was aware of Fischhoff's preliminary motion to

designate certain species claims as not corresponding to generic Count 2, a motion uncontested by Adang.

Moreover, we fail to comprehend why it was reasonable for Adang to presume that a request to file additional motions in response to the APJ's express order inviting just such a request "would clearly have been premature under the APJ's rationale set forth in the Order redeclaring the interference (Paper No. 148, pages 30-32)" (AB 62-63, bridging para.). The reasonableness of Adang's presumption, i.e., that it could not file its motion for judgment and discovery before Monsanto elected the first to invent the invention of Count 2 as between Barton and Fischhoff, vanished when the APJ ordered the parties to specify what additional preliminary motions, if any, needed to be filed in the newly declared interference with Barton as a party and new Count 2 and to explain why any additional preliminary motions specified and supporting evidence are necessary to, and should be filed in, this interference.

Even if we were to assume that Adang's untimely response must be excused for good cause, Adang still has not explained why the additional preliminary motion is justified by Barton's reinstatement as junior party to this interference, Count 2, or Monsanto's election of Fischhoff as first to invent the invention of Count 2 as between Barton and Fischhoff. The APJ considered

all of the arguments presented in support of Adang's belated request (Paper No. 212) and properly denied the request.

On July 18, 2003, Fischhoff filed Monsanto Election pursuant to 37 CFR § 1.602(a) designating "Junior Party Fischhoff et al. as first to invent, vis-a-vis the Junior Party Barton et al., the subject matter defined by Count 2" (Paper No. 182). Fischhoff hereinabove has been determined to be the first to invent the subject matter of Count 2 of this interference, based on the evidence of record and Monsanto's election of Fischhoff as first to invent the subject matter of Count 2 as between Barton and Fischhoff, judgment on priority of the invention of Count 2 shall be entered against Adang and nonelected Barton. Barton's claims designated as corresponding to Count 2 are unpatentable to Barton under 35 U.S.C. § 102(g)/103 in view of the claims of Fischhoff's involved application at least in-part defining Count 2. Nevertheless, Adang argues that the interest of justice still requires consideration of the issue of priority between Barton and Fischhoff because "[v]ery little was known regarding the inventive activities of Kenneth Barton and Michael Miller" at the outset of this interference, i.e., on November 7, 1996, and much has changed in 6 years (AB 63). Specifically, Adang states (AB 63-64, bridging para.):

In Delaware II litigation, the Court of Appeals for the Federal Circuit affirmed that the invention of Kenneth

Barton and Michael Miller in 1987 invalidated certain claims of Fischhoff's U.S. Patent No. 5,500,365, which issued from the parent of the Fischhoff application involved in this interference.

The invention of Count 2 of this interference is far broader than the invention defined by Claims 7-9 and 12 of Fischhoff's U.S. Patent 5,500,365 which were at issue in Delaware II.

Second, Fischhoff's U.S. Patent 5,500,365 is not involved in this interference and no claim thereof is, or has ever been, designated as the same patentable invention as Count 2 of this interference. Third, the evidence of record shows that Fischhoff first conceived of the invention of Count 2 prior to "the invention of [Claims 7-9 and 12 of U.S. Patent 5,500,365] of Kenneth Barton and Michael Miller in 1987" (AB 63-64).

Adang further argues (AB 63-64, bridging para.):

Barton has remained a party in the interference through to Final Hearing. Nonetheless, Monsanto did not file a preliminary statement or a case-in-chief on behalf of Barton and, therefore, the interference record is devoid of any record reflecting the basis upon which Monsanto determined Fischhoff to be prior inventor of Count 2 vis-a-vis Barton.

Additional discovery is authorized under the interference rules, but it must be shown that the interest of justice requires the discovery, and the motion must be timely. 37 CFR § 1.687(c). While Adang argues that a great deal of knowledge has been acquired in the six (6) years since this interference was initiated, none of that knowledge appears to have been cited or

relied upon in support of its request to file a new, or refile a, belated motion under 37 CFR § 1.633(a) for judgment and possible discovery that Fischhoff's claims corresponding to Count 2 are unpatentable under 35 U.S.C. § 102(g)/103 in view of the possibility of Barton's prior invention thereof.

Adang has not shown how the interest of justice requires further delay and further burdening Monsanto with discovery or remanding the case to the primary examiner. Nor has Adang provided any plausible reason to suspect Monsanto did not in good faith elect Fischhoff, as between Barton and Fischhoff, as first to invent the subject matter of Count 2 of this interference. We agree with the APJ that Adang's suspicions are too thin a basis to justify the "possible" discovery it seeks or show good cause why its belated request should be honored. Adang has failed to show that the APJ's decision was an abuse of discretion. Adang's requests stand DENIED.

6. Fischhoff Motion to Suppress Evidence

We have endeavored to consider all the documentary and testimonial evidence and arguments filed in support of the parties' arguments and positions in this interference. We have been especially considerate of the specific documentary and testimonial evidence to which Adang points in support of its arguments. Moreover, Fischhoff's Motion To Suppress Evidence

(Pursuant to 37 CFR § 1.656(h)) itself invites us to peruse the very evidence Fischhoff would have us suppress. Having considered all the evidence submitted by the parties which is particular to this interference and all the evidence submitted by the parties common to this interference and the Delaware I, Delaware II, and California infringement cases and appeals identified herein, we are convinced that the evidence as a whole does not show that Adang and Barton are entitled to patents claiming the subject matter of their claims designated as corresponding to Count 2; Fischhoff's uncontested Preliminary Motion 10 (Paper No. 88) should be, and has been, granted; and Adang's Request For Authorization To Address The Unpatentability Of Fischhoff's Claims And To Obtain Related Discovery (Paper No. 199) properly was denied (Paper No. 212). Therefore, Fischhoff Motion To Suppress Evidence (Pursuant To 37 CFR § 1.656(h)) (Paper No. 248) is dismissed as moot.

DISMISSED.

7. Final Disposition of Interference 103,781

Priority of the invention defined by new Count 2 of this interference has been determined against Senior Party Adang and Junior Party Barton based on all the evidence of record.

Accordingly, it is

ORDERED that Junior Party Fischhoff's Preliminary Motion

No. 10 (Paper No. 88) under 37 CFR § 1.633(c)(4) to redefine

the subject matter of the interference by designating

(1) Claims 41-43 of Fischhoff's involved U.S. Application

08/434,105, filed May 3, 1995, and (2) Claims 13-14 of Adang's

U.S. Patent 5,380,831 (FX 11), issued January 10, 1995, as not

corresponding to Count 2, is GRANTED;

FURTHER ORDERED that:

Interference 103,781 is redeclared as Junior Party KENNETH

A. BARTON and MICHAEL J. MILLER (U.S. Application 07/827,906) or

Junior Party DAVID A. FISCHHOFF and FREDERICK J. PERLAK (U.S.

Application 08/434,105) v. Senior Party MICHAEL J. ADANG, THOMAS

A. ROCHELEAU, DONALD J. MERLO, and ELIZABETH E. MURRAY (U.S.

Patent 5,380,831), with new Count 2 directed to:

Any one of Claims 1-4, 7, and 15-22 of Barton et al.'s Application 07/827,906, filed January 30, 1992;

- or -

Any one of Claims 3, 5, 39 and 40 of Fischhoff et al.'s Application 08/434,105, filed May 3, 1995;

- or -

Any one of Claims 1-12 of Adang et al.'s
U.S. Patent 5,380,831, which issued January 10, 1995,
from U.S. Application 08/057,191, filed May 3, 1993.

FURTHER ORDERED that Claims 41-43 of Fischhoff's involved U.S. Application 08/434,105, filed May 3, 1995, and

(2) Claims 13-14 of Adang's involved U.S. Patent 5,380,831, issued January 10, 1995, are designated as not corresponding to new Count 2;

FURTHER ORDERED that, on the record before the Board of Patent Appeals and Interferences, judgment on priority of the invention of new Count 2, the sole count in this interference, is awarded against Senior Party MICHAEL J. ADANG, THOMAS A. ROCHELEAU, DONALD J. MERLO, and ELIZABETH E. MURRAY;

FURTHER ORDERED that, on the record before the Board of Patent Appeals and Interferences, judgment on priority of the invention of new Count 2, the sole count in this interference, is awarded against Junior Party KENNETH A. BARTON and MICHAEL J. MILLER;

FURTHER ORDERED that, on the record before the Board of Patent Appeals and Interferences, judgment on priority of the invention of new Count 2, the sole count in this interference, is awarded in favor of Junior Party DAVID A. FISCHHOFF and FREDERICK J. PERLAK;

FURTHER ORDERED that, on the record before the Board of Patent Appeals and Interferences, Senior Party MICHAEL J. ADANG, THOMAS A. ROCHELEAU, DONALD J. MERLO, and ELIZABETH E. MURRAY is not entitled to a patent containing Claims 1-12 of U.S. Patent 5,380,831, issued January 10, 1995;

FURTHER ORDERED that, on the record before the Board of Patent Appeals and Interferences, Junior Party KENNETH A. BARTON and MICHAEL J. MILLER is not entitled to a patent containing Claims 1-4, 7, and 15-22 of Barton's U.S. Application 07/827,906, filed January 30, 1992;

FURTHER ORDERED that Senior Party Adang's Request For Authorization To Address The Unpatentability Of Fischhoff's Claims And To Obtain Related Discovery (Paper No. 199) is DENIED;;

FURTHER ORDERED THAT Fischhoff's Motion To Suppress Evidence (Pursuant To 37 CFR § 1.656(h)) (Paper No. 248) is <u>DISMISSED</u>;

FURTHER ORDERED that Junior Party Fischhoff's deferred Preliminary Motion 5 (Paper No. 82) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 are unpatentable under 35 U.S.C. § 112, first paragraph (enablement requirement), is <u>DISMISSED</u>; and

FURTHER ORDERED that Junior Party Fischhoff's deferred Preliminary Motion 7 (Paper No. 85) under 37 CFR § 1.633(a) for judgment that Claims 1-12 of Adang's U.S. Patent 5,380,831 are unpatentable under 35 U.S.C. § 102 or § 103 is <u>DISMISSED</u>.

It is also

ORDERED that, if there is a settlement and it has not been filed, attention is directed to 35 U.S.C. \$ 135(c) and 37 CFR \$ 1.661; and

FURTHER ORDERED that a copy of this decision be given an appropriate paper number and entered into the file records of BARTON Application 07/827,906; FISCHHOFF Application 08/434,105; and ADANG U.S. Patent 5,380,831, which issued January 10, 1995, from U.S. Application 08/057,191.

TEDDY S. GRON

TEDDY S. GRON)
Administrative Patent Judge)

CAROL A. SPIEGEL

Administrative Patent Judge)

APPEALS AND
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